

From: Aubrey, Craig
To: [Cathy Tortorici - NOAA Federal](#); [Gina Shultz](#); [James Cowles](#); [Michael Goodis](#); [Patrice Ashfield](#); [Richard Keigwin](#); [Kunickis, Sheryl - OSEC](#); [Susan Lewis](#); [Yu-Ting Guilaran](#); [Pease, Anita](#)
Subject: Fwd: Pesticide scheudle for tommorow's discussion
Date: Thursday, August 04, 2016 9:43:33 AM
Attachments: [Draft timelines & tasks 07-20-2016 NMFS FWS EPA.xls](#)

this is the version we discussed today

Craig

DRAFT_Timeline for BiOp on Chlorpyrifos, Diazinon, and Malathion	
BiOp Method development with interagency group	June-September 15
Acquire all needed exposure values and maps	August 2016
Consultation History	October 2016
Approach to Assessment	November 2016
Status of the species (and critical habitat)	NMFS = December 2016; FWS = March 2017
Environmental baseline	December 2016
EPA Review of Status and Baseline	January 2017
Analyze lines of evidence	January 2017
Effects Analyses for Species and Effect Analyses for Critical Habitat	January 2017
Cumulative Effects	January 2017
Integration and Synthesis complete	March 2017
RPMs/RPAs/ITS complete	March 2017

RPMs/RPAs/ITS Discussion with EPA	March 2017
Draft ready for Internal Review (OPR/GC/)	April 2017
Draft BiOp complete	May 2017
Review and Comments Back from EPA and others	June/July 2017
Reconcile/consider comments	July - September 2017
Review by OPR / GC/ others	October 2017
Revise and format	November 2017
Final BiOp	December 2017

(DRAFT) Method development for Biological Opinion: Collaborative interagency work with NMFS EPA and FWS

BIOLOGICAL OPINION SECTION	COMPONENTS OF EACH SECTION	ACTIVITIES	STAFF ASSIGNED (NMFS; EPA; USFWS)	START DATE	DRAFT DUE DATE
Aquatic Exposure: (Lead: TONY- Pesticides) (Lead: THOM- Species and habitats) George (aquatic) & EPA: Chuck (aquatic)	<p>_How many individuals are exposed/ proportion of population exposed?</p> <p>_Overlay pesticides with life-history of species to determine proportion of population exposed</p> <p>_Draft and document procedure for inclusion in "Approach to the Assessment"</p>	<p>GENERAL EXPOSURE (for both aquatic and terrestrial): 1) Determine temporal aspect of EECs to bring into analysis; 2) Determine if and how to incorporate use into analysis (eg, application rate, timing, 1) EECs for habitats at variety of distances (98.42 ft (30 meter) increments up to 1000 and 2600 ft); 2) How to include downstream dissipation in flowing water habitats? 3) Review NLAAs using what we know about exposure 4) temporal EEC info</p>	<p>NMFS: Cathy, David, Ryan, Julann, Thom, Tony EPA: Chuck Melissa FWS: Karen Sara Chris Mebane</p>	Began in June	9/15/2016
Terrestrial Exposure: Leads: FWS: NANCY EPA: Melissa	<p>_How many individuals are exposed/ proportion of population exposed?</p> <p>_Overlay pesticides with life-history of species to determine proportion of population exposed</p> <p>_Draft and document procedure for inclusion in "Approach to the Assessment"</p>	<p>GENERAL EXPOSURE (for both aquatic and terrestrial): 1) Determine temporal aspect of EECs to bring into analysis; 2) 1) Preferred habitat types (GAP analysis); 2) EECs for spray drift deposition; 3) distribution of species within range</p>	<p>FWS: Keith Moira Leona Kate (plants) EPA: Colleen Elizabeth</p>	Began in May	9/15/2016
Magnitude of response for each line of evidence NMFS: CATHY FWS: SARA EPA: COLLEEN/AMY	<p>_At any given exposure what are the anticipated effects? Combine life history information with dose response data</p> <p>_Review toxicity studies and develop dose-response relationships when appropriate for a line of evidence for a species/taxa (grouping)/(e.g.) small tooth sawfish</p> <p>_Draft and document procedure for inclusion in "Approach to the Assessment"</p>	To be developed	<p>NMFS: Cathy, Scott, Julann, David FWS: Moira, George, Nancy EPA: Colleen, Amy</p>	Beginning July 11	9/15/2016
Mixtures Leads: NMFS: DAVID/TONY FWS: EPA: CHUCK/ED O	<p>_Mixture example with formulations; overall strategy with mixtures; includes both exposure</p> <p>_Draft and document procedure for inclusion in "Approach to the Assessment"</p>	<p>1) Develop aquatic example; 2) Develop terrestrial example</p>	<p>NMFS: David, Tony, Scott FWS: EPA: Chuck, Ed O</p>	Beginning July 13 FWS no longer involved in this	
Population level assessment Leads: NMFS: JULANN/SCOTT FWS: KEITH/ANDY EPA: KRIS/JEN	<p>_Carry forward example with smalltooth sawfish to evaluate population and species level effects from lines of evidence.</p>	To be developed	<p>NMFS: Julann, Scott, David FWS: Chris Mebane, Leona EPA: Kris, Jen</p>	Beginning July 13	9/15/2016

(DRAFT) Method development for Biological Opinion: Collaborative interagency work with NMFS EPA and FWS

BIOLOGICAL OPINION SECTION	COMPONENTS OF EACH SECTION	ACTIVITIES	STAFF ASSIGNED (NMFS; EPA; USFWS)	START DATE	DRAFT DUE DATE
	_Draft and document procedure for inclusion in "Approach to the Assessment"				
Weight of evidence assessment in Integration and Synthesis Leads: NMFS: SCOTT FWS: KAREN EPA: COLLEEN/KRIS/ELIZABETH/ED O	_For risk modifier component and lines of evidence work through metrics _Draft and document procedure for inclusion in "Approach to the Assessment"	Develop metrics for line of evidence/ environmental baseline/ status of the species; develop methodology for aggregating lines of evidence; Work through species and habitat score card with example species	NMFS: Scott, David, Cathy, Ryan, Julann, Tony, Thom FWS: Nancy, Kate EPA: Colleen, Kris, Elizabeth, Ed O	Beginning July 13	9/15/2016
Mitigation/Conservation measures, monitoring , tracking take Leads: NMFS: SCOTT FWS: Andy Leona EPA: BILL/CHUCK/AMY/KHUE	_What potential mitigation/conservation measures are available for aq species? How do they differ for the different bins? _What potential mitigation/conservation measures are available for terrestrial species? How do they differ for the different taxa? _How will the mitigation/conservation measures be translated to the label? Will they be feasible? _Draft and document procedure for inclusion in "Approach to the Assessment" _Condidder baseline enhancement, avoidance, minimization	Develop a methodology for assessing and implementing mitigation/conservation measures for different taxa. Incorporate into EPA labels mitigations already negotiated in BiOps by federal land management agencies. Ensure and demonstrate that mitigation/conservation measures are protective of the species (i.e., lower EECs) and are feasible. Ensure that development of mitigation/conservation measures is transparent and reproducible for public.	NMFS: Thom FWS: Karen Keith Kate EPA: Bill, Chuck, Amy, Khue	Beginning July 12	9/15/2016

NMFS FWS EPA Draft Biological Opinion on chlorpyrifos, diazinon, malathion						KEY: author = writes the bulk of section reviewer = edits/comments		KEY: author = writes the bulk of section reviewer = edits/comments		FWS POCs: DIAZ: Karen MALA: Keith CHLOR: Leona/Andy		
BIOLOGICAL OPINION SECTION	COMPONENTS	ACTIVITIES (DEVELOPED WITH INTERAGENCY GROUPS WHEN APPROPRIATE)	INFORMATION IN BES (YES/NO)	COLLABORATIVE EFFORT TO ADDRESS INFORMATION NEEDS/GAPS	NMFS STAFF (author or reviewer)	START DATE	NMFS DRAFT DUE DATE	FWS STAFF (author or reviewer)	FWS DRAFT DUE DATE	EPA REVIEW COMPLETION DATE	RELATED ACTIVITIES & SUBCOMPONENTS (e.g. LEGAL REVIEW)	COMMENTS
Background/Introduction	History		Some info	NA	DIAZ: Thom (author) MALA: Thom (author) CHLOR: Thom (author)	9/26/2016	10/10/2016	DIAZ: Karen (reviewer) MALA: Keith (reviewer) CHLOR: Andy (reviewer)	10/10/2016	10/24/2016		This component could be done anytime as it doesn't depend on other task being completed
Consultation History	Consultation timeline and activities	Document history of consultation	Some info	NA	Thom (reviewer)	NMFS: 9/26/2016 (FWS: completed to date)	ongoing	Sara (author)	completed to date	5/1/2017	legal review	This is an ongoing section and will be updated as the consultation progresses; Ask EPA if they would like to see an early draft.
Description of Proposed Action		Verify what's in BE	YES	Work with EPA to determine any changes	DIAZ: Tony (reviewer) MALA: Tony (reviewer) CHLOR: Tony (reviewer)	Now	NMFS response on draft CHLOR due 8/15/2016	DIAZ: Karen (author) MALA: Keith (author) CHLOR: complete	DIAZ: 9/15/2016 MALA: 9/15/2016 CHLOR: complete; ready for NMFS review	10/15/2016		Any changes to DOA need to be incorporated in final BiOp, so this activity is ongoing depending on results from pesticide registrant label changes.
Action Area		_Verify what's in BE _Maps	YES	Work with EPA to determine any changes	DIAZ: Ryan (author) MALA: Ryan (author) CHLOR: Ryan (author)	9/26/2016	ongoing	DIAZ: Karen (reviewer) MALA: Keith (reviewer) CHLOR: Andy (reviewer)	ongoing	10/24/2016		incorporated in final BiOp, so this activity is ongoing depending on results from pesticide registrant label changes.
Approach to Assessment	Chlorpyrifos, diazinon, malthion Mode of action	Incorporate method development from summer work	Some info	Work with EPA;FWS	DIAZ: Scott (reviewer) MALA: Scott (reviewer) CHLOR: Scott (reviewer)	10/3/2016	10/17/2016	DIAZ: Karen (author) MALA: Keith (author) CHLOR: Chris Mebane (author)	10/17/2016	11/1/2016		This section is based on summer's method development
Status of Species	Salmon and trout (29) (NMFS)				Ryan, Thom	TBD	TBD	SOS: Chris Mullen (Leona, Keith,Karen, Andy) SoCH: Chris Mullen (Leona, Karen, Keith, Andy)		TBD		
	Smelt (1) (NMFS)				Ryan, Thom	TBD	TBD			TBD		
	Sturgeon (8) (NMFS)			Seek EPA review on a few species such as gulf and shortnose sturgeon	Ryan, Thom	Now	6/1/2016			6/15/2016		We'll send a few species this summer so EPA can see what information
	Rockfish (3)				Ryan, Thom	TBD	TBD			TBD		
	Sawfish and sharks (2)			Seek EPA review on sawfish	Ryan, Thom	Now	6/1/2016			6/15/2016		
	Abalone (1)				Ryan, Thom	TBD	TBD			TBD		
	Turtles (9)				Ryan, Thom	TBD	TBD			TBD		
	Whales (1)				Ryan, Thom	TBD	TBD			TBD		
	Plants (NMFS: 1) (FWS: 886)				Ryan, Thom	TBD	TBD		TBD: NMFS; 3/1/2017, FWS	TBD		
	Seals and sea lions (5)				Ryan, Thom	TBD	TBD			TBD		
	corals (22)				Ryan, Thom	TBD	TBD			TBD		
	Birds (110)								3/1/2017			
	FWS fishes (141)								3/1/2017			
	Mussels (95)								3/1/2017			
	Terrestrial Mammals (90)								3/1/2017			
	Terrestrial Invertebrates (131)								3/1/2017			
	FWS Marine Mammals (5)								3/1/2017			

NMFS FWS EPA Draft Biological Opinion on chlorpyrifos, diazinon, malathion						KEY: author = writes the bulk of section reviewer = edits/comments		KEY: author = writes the bulk of section reviewer = edits/comments		FWS POCs: DIAZ: Karen MALA: Keith CHLOR: Leona/Andy		
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	Aquatic Invertebrates (no Mussels; 81)								3/1/2017			

NMFS FWS EPA Draft Biological Opinion on chlorpyrifos, diazinon, malathion					KEY: author = writes the bulk of section reviewer = edits/comments			KEY: author = writes the bulk of section reviewer = edits/comments			FWS POCs: DIAZ: Karen MALA: Keith CHLOR: Leona/Andy	
BIOLOGICAL OPINION SECTION	COMPONENTS	ACTIVITIES (DEVELOPED WITH INTERAGENCY GROUPS WHEN APPROPRIATE)	INFORMATION IN BES (YES/NO)	COLLABORATIVE EFFORT TO ADDRESS INFORMATION NEEDS/GAPS	NMFS STAFF (author or reviewer)	START DATE	NMFS DRAFT DUE DATE	FWS STAFF (author or reviewer)	FWS DRAFT DUE DATE	EPA REVIEW COMPLETION DATE	RELATED ACTIVITIES & SUBCOMPONENTS (e.g. LEGAL REVIEW)	COMMENTS
Status of Critical Habitat	Amphibians (40)								3/1/2017			
	Reptiles (49)								3/1/2017			
	All Status sections compiled				Ryan, Thom	Now	12/17/2016		3/1/2017	TBD	1/2/2017	Complete draft of status section and review by EPA
	All species							Leona, Chris Mullen (Keith, Karen)	TBD			
Environmental Baseline					Thom		10/15/2016	DIAZ: Andy/Jeff MALA/CHLOR: John/Andy	TBD	TBD	11/15/2017	
Effects of Proposed Action					All	ongoing	1/15/2017	All		2/15/2017		
Develop exposure characterization	Apply EDMs and corresponding eecs to species and habitat ranges		some info		All	10/3/2016	1/3/2017			1/15/2017		
Determine risk to individual fitness based on BEs and magnitude of response	Review of toxicity studies to identify magnitude of response		some info	Work with EPA/FWS to review studies	All	10/3/2016	12/2/2016			12/16/2016		
Determine how many individuals are likely affected based on overlap of use sites and off-site movement with species/habitat life history					All	TBD	TBD			TBD		
Determine whether population-level effects are anticipated by evaluating each line of evidence					All	TBD	TBD			TBD		
Weigh each line of evidence using weight of evidence metrics					All	TBD	TBD			TBD		
Cumulative Effects					Thom (author)	11/15/2016	1/15/2017	TBD (Keith, Karen, Andy)		TBD		
Integration and Synthesis Species	Summaries of individual a.i.s				All	2/15/2017	3/15/2017	TBD (Karen, Keith, Andy, Leona)		TBD		
Integration and Synthesis Critical Habitat	Summaries of individual a.i.s				All	2/15/2017	3/15/2017	TBD (Karen, Keith, Andy, Leona)		TBD		
	Species specific evaluations				All	2/15/2017	3/15/2017			TBD		
Conclusions: Score cards	a.i. specific				All	3/15/2017	3/22/2017	TBD; All		TBD		
RPM	Elements				All	3/15/2017	3/31/2017			TBD		
RPA	Elements				All	3/15/2017	3/31/2017			TBD		
ITS	Amount and Extent of take				All	3/15/2017	3/31/2017	TBD		TBD		
Executive Summary, Review, Formatting					All	5/1/2002	5/31/2017			TBD		
DRAFT Biological Opinion Released to EPA on 5/31/2017												

			Response to Comments 7/14/2016		
BIOLOGICAL OPINION SECTION (Grand Bargain Pesticides)	Description (note: each chemical will have a separate biological opinions. Some sections will carry over between opinions, as appropriate)	Milestones, status and due dates			
Background (Introduction)	Introduction to the biological opinion, including a brief generalized history of pesticide registration under FIFRA and ESA Section 7. Will include a very brief overview of the request to the National Academy of Sciences and release of the NAS recommendations, interim measures, etc.	in process, due 10/10/2016	<p><i>Staff has begun discussions on how to move forward. For some sections, i.e. Description of the action and Consultation history, drafts have been prepared. Leads have been identified for consultation history, description of the action and action area.</i></p> <p><i>We currently have a one page summary of the NAS study/report in the draft consultation history. If needed, we can provide a more detailed description in an appendix.</i></p>		
Consultation History	Short overview of the consultation history starting with mention of the NAS request and results of their review. Also includes meetings with other agencies, coordination on biological evaluations, interagency and stakeholder workshops, etc.	1st draft complete, ready for NMFS review due 8/1/2016	<p><i>The time frame for the consultation history begins in 2010 when the NAS was asked to exam the scientific and technical issues associated with determining the risk of pesticide registration and use to threatened and endangered species protected by the ESA. Subsequent topic areas are the stakeholder and interagency workshops as well as key milestones in the process; mention of weekly steering committee calls w agenices, draft BE release, status reports to congress, etc.</i></p>		
Description of Proposed Action	Abridged description of the proposed action, with excerpts from the biological evaluation for each chemical. Some summarizing to provide better flow and highlight any themes that will be important in the biological opinion. Will include the full biological evaluation description of the action by reference.	DIAZ: 9/15/2016 MALA: 9/15/2016 CHLOR: complete; ready for NMFS review	<p><i>Karen, Leona and Keith drafted a description of the proposed action for chlorpyrifos. It is a much shortened version of EPA's and references back to the BE for more detail. Our plan was to share with NMFS and agree on the final description of the action for chlorpyrifos, and then use that as a template for the other 2 chemicals</i></p>		
Action Area	Abridged description of the proposed action area with map(s)--i.e., the entire country and territories for malathion and chlorpyrifos, with some refinements for diazinon	ongoing	<p><i>This will be a shortened version of what's in EPA's BE. We will provide the regulatory definition of the action area and briefly describe how the action area was derived for each chemical. For example, the action area for chlorpyrifos was established by mapping use sites as defined by the product labels and determining the extent of potential offsite transport. For chlorpyrifos and malathion, the action area includes the entire U.S. and its territories. Diazinon has a much smaller footprint due to its more limited use. We will reference the BE for the more technical information on how the extent of the offsite transport was determined.</i></p>		
Approach to Assessment	This section will be provide an overview of how the effects of the action will be considered along with the other sections of the opinion. A large part of this section will focus on how the effects section will be layed out, and will be developed during the Summer Working Groups sessions on the Tasks tabs. This will be a joint effort between EPA, NMFS, and USFWS	all methods for approaches are due 9/15/2016	<p><i>The approach to the assessment lays out the framework of methodologies that will be used to assess risks to listed species and their critical habitats, develop mitigation/conservation measures and methods to monitor and report on pesticide use and incidental take. It will incorporate status of the species/critical habitat and the environmental baseline into the effects analysis methods. Workgroups have been established to develop these methodologies which expand beyond the scope of the effects analysis.</i></p>		
Aquatic Exposure	Identified tasks to be discussed for subsequent meetings such as use data,				
Terrestrial Exposure	Identified tasks to be discussed for subsequent meetings such as use data, timing of application and percent of crops sprayed.				
Magnitude of Response	Met 7/11/2016.				
Population Level Assessment (PLA)	Met jointly with WOE 7/13/2016				
Weight of Evidence (WOE)	Met jointly with Population level assessment group				

Mitigation/Conservation Measure, Monitoring & Tracking Take (MCMMTT)	Met 7/12/2016			
Status of Species	Text in BiOp will refer to two separate appendices for (1) species and (2) critical habitats. Final product will be 2 to 3 pages per species, different format for SoCH, based on how the information is being compiled from FESTF through Chris	All 1,642 Status of Species documents will be complete by March 2017		
Environmental Baseline	This section will be a 50,000 ft overview of the environmental baseline for all species, considered collectively, and not on species by species basis. (SOS appendices are intended to address threats and other species-specific environmental baseline issues.). Since the action area is so vast, we will focus on trends related to threats and stressors, particularly those that intersect with water quality and quantity, habitat, etc. Plan to generally describe examples of baseline issues, such as the biodiversity (and listed species) hotspots, such as the SE US, drought in SW, etc. This helps to set the stage for the remainder of the BiOp.	Ramping up to begin	Information provided in the non-species specific environmental baseline will provide an overview of general threats facing listing species, such as pesticide use, agriculture, water quality, habitat destruction, climate change, etc. as a means to focus on groups of species/critical habitats (i.e., PCEs) rather than focusing on threats to individual species/critical habitat. For example, pesticides have been documented in the majority of water bodies throughout the U.S., so instead of identifying individual species, we will gear the discussion towards all aquatic species and the potential threats they are currently facing.	
Effects of Proposed Action	Use a similar format to the biological evaluation approach (coordinate with EPA and NMFS so that sections will be similar); this is in part the detailed output of the Summer Working Groups (Exposure Characterization, Magnitude of Response, Mixtures, Population-level Assessment, Weight of Evidence, Mitigation Measures and Monitoring) and implementation of the resulting methodologies.	Ramping up to begin (after stakeholders meeting)	We will coordinate with USDA on appropriate topics. USDA typically participates in our steering committee meetings and in those meetings that typically focus on specific discussions on how the pesticides are used, usage data, monitoring data, and mitigation/conservation measures. It will be appropriate for USDA to attend our mitigation/conservation measures and monitoring workgroup.	
Cumulative Effects	General overview of the anticipated cumulative effects in the action area. Will be similar in format/style the environmental baseline, but anticipated to be much shorter.	TBD		
Integration and Synthesis Species & Critical Habitat	Expanded version of the information immediately preceding and forming the basis for our conclusion. This will be its own section, but will immediately precede the CONCLUSION section in an effort to simplify the reading of the conclusion. The Integration and Synthesis section will weave together all the different parts of the biological opinion to "tell the story" that forms the basis behind our conclusion(s).	TBD	We will be using species/critical habitat (e.g., PCEs) groupings to the greatest extent possible. For example, since toxicity to amphibians is likely to be the same (we only have data for frogs; not toads or salamanders) effects will be characterized by the exposure pathway which can be represented by groups of amphibians (terrestrial only, aquatic only, both terrestrial and aquatic). For plants, which are largely impacted through indirect effects, e.g., effects to pollinators; we will focus on the impacts to pollinators as a whole to describe impacts to plants.	
Conclusions: Score cards	The conclusion section will outline the JAM/NoJAM conclusions for the species. We will attempt to simplify and collate the calls according to taxa groups and/or geographic groupings to the extent appropriate and possible to avoid repetitive elements as much as possible. "Scorecards" are a NMFS element, haven't decided if we will do this yet. It may be worth considering, though.	TBD		
RPM	Measures needed to minimize take	TBD		
RPA	If there are jeopardy conclusions	TBD		
ITS	Amount and Extent of take; As with the Conclusion section, we will attempt to simplify and collate as much as possible	TBD		
Executive Summary, Review, Formatting				

From: Kunickis, Sheryl - OSEC
To: [Schroeder, Jill](#); [Hill2, Elizabeth - ARS](#); [Chin, Teung](#); [Domesle, Alexander - ARS](#); [Abbott, Linda - OCE](#); [Fajardo, Julius](#); [Schechtman, Michael](#); [Epstein, David](#)
Subject: Fwd: PPDC Agenda and Materials
Date: Friday, October 21, 2016 2:10:54 PM
Attachments: [Final Agenda for November 2016 PPDC Meeting.docx](#)
[ATT00001.htm](#)
[Session 7b ESA Implementation Update.docx](#)
[ATT00002.htm](#)
[Session 7c Epi Framework Update.docx](#)
[ATT00003.htm](#)
[Session 7d PRIA 4 Update.docx](#)
[ATT00004.htm](#)
[Session 7e Resistance Management Update.docx](#)
[ATT00005.htm](#)
[Session 7f Chlorpyrifos Update.docx](#)
[ATT00006.htm](#)
[Session 7g Glyphosate Update.docx](#)
[ATT00007.htm](#)

Looks like a loaded agenda. I can already think of questions for the items listed below! C&T is a topic - could be interesting. DO NOT SHARE this copy. While it will be out, I don't want anyone to say USDA shared it.

Cheers,
Sheryl

Sent from my iPad

Begin forwarded message:

From: "Zimmerman, Dea" <Zimmerman.Dea@epa.gov>
Date: October 21, 2016 at 1:59:18 PM EDT
To: Undisclosed recipients;;
Subject: PPDC Agenda and Materials

Dear PPDC Members –

Attached please find the agenda for the November 2-3 PPDC meeting taking place in the first floor conference center in the Potomac Yards South building located at 2777 S. Crystal Drive, Arlington, VA 22202.

Similar to the May 2016, there is a session at 9:00 am on Thursday November 3rd, where OPP managers and staff will be available to discuss questions you may have on selected topics. The session is:

9:00-10:30 7. Question and Answer Session to Topic Updates Sent in Advance of Meeting

Session Chairs: OPP Senior Leadership Team

Session Goal: Answer questions from PPDC members on:

<!--[if !supportLists]-->a. <!--[endif]--> *Acute 6-Pack Testing Alternatives*

<!--[if !supportLists]-->b. <!--[endif]-->*Endangered Species Act
Implementation Update*
<!--[if !supportLists]-->c. <!--[endif]-->*Epidemiological Framework*
<!--[if !supportLists]-->d. <!--[endif]-->*Pesticide Registration
Improvement Act (PRIA) 4*
<!--[if !supportLists]-->e. <!--[endif]-->*Resistance Management*
<!--[if !supportLists]-->f. <!--[endif]-->*Chlorpyrifos*
<!--[if !supportLists]-->g. <!--[endif]-->*Glyphosate*

OPP has prepared summaries for each topic, all of which are attached except the “Acute 6-Pack Testing Alternatives”. I will pass this one along by early next week at the latest. Please review these materials in advance of the meeting and come prepared with any questions you may have.

I will also post presentation materials for the rest of the sessions to the PPDC website, hopefully by mid-week, and let you know when that is done.

<https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc>

Entering Potomac Yards – please give yourself some extra time.

As a reminder and for those who have never been to Potomac Yards, you will need to go thru security screening to enter the building. You will need to present photo identification to the security guards, sign in and go through the metal scanners. Due to the REAL ID Act, Driver’s licenses may not be accepted from **Minnesota, Missouri and Washington** (people from these states can use a passport or an official state identification badge). You do not need an escort for the full PPDC meeting happening in the lobby level conference room. I will give the building security guards a list with your name on it to try to expedite your entrance.

If something has come up and you will not be attending the PPDC, please let me know (regrets only). Also please let me know if you will be participating remotely by phone. Safe travels and I look forward to seeing everyone.

Regards,

Dea

Dea Zimmerman
Pesticide Program Dialogue Committee, DFO
Zimmerman.dea@epa.gov
312-353-6344



PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA

Conference Line: 1-866-299-3188; Conference Code: 312-353-6344 #

Wednesday, November 2, 2016

9:00-9:20 **Welcome and Opening Remarks**

*Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention
Jack Housenger, Director, Office of Pesticide Programs*

9:20-9:30 **Introductions by PPDC Members**

9:30-10:30 **1. OPP's Role in Agricultural Biotechnology Today and Tomorrow**

Session Chair: Robert McNally, Director, Biopesticides and Pollution Prevention Division

Mike Mendelsohn, Senior Regulatory Advisor, BPPD

Elizabeth Milewski, Senior Science Advisor, BPPD

Session Goal: *Discuss new technologies for pest control and the role the government, and specifically OPP, will play in ensuring adequate regulation.*

9:30-10:00 EPA

10:00-10:30 PPDC Discussion

10:30-10:45 **Break**

10:45-11:45 **2. Zika Update**

Session Chair: Arnold E. Layne, Deputy Director, Office of Pesticide Programs

Session Goal: *Provide an update on OPP's activities since May and discuss regulatory challenges to address the issue of mosquito control.*

10:45-11:00 EPA

11:00-11:45 PPDC Discussion

11:45-1:15 **Lunch**

1:15-2:15 **3. Pollinator Protection Updates: Acute Bee Mitigation Proposal and Neonicotinoid Risk Assessment Schedule**

Session Chairs: Michael Goodis, Acting Director, Registration Division

Yu-Ting Guilaran, Director, Pesticide Re-evaluation Division

Marietta Echeverria, Chief, Invertebrate-Vertebrate Branch I, Registration Division

Session Goal: *Provide an update on the acute bee mitigation proposal and the risk assessment schedule for the neonicotinoid active ingredients.*

1:15-1:45 EPA

1:45-2:15 PPDC Discussion

2:15-2:45 **4. Update from the Pollinator Protection Plan Metrics Workgroup**

Session Chair: *Michael Goodis, Acting Director, Registration Division*

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING – p. 2

**Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA
Conference Line: 1-866-299-3188; Conference Code: 312-353-6344 #**

Session Goal: Provide the PPDC a current status of this workgroup.

2:15-2:30 EPA

2:30-2:45 PPDC Discussion

2:45-3:00 Break

3:00-3:45 5. Updates on the Certification of Pesticide Applicators Rule and Implementation Activities of the Revised Worker Protection Standard

Session Chair: Kevin Keaney, Chief, Certification and Worker Protection Branch, Field and External Affairs Division

Session Goal: Discuss the Agency's ongoing efforts to protect farmworkers through updates on the progress for implementing the Worker Protection Standard Rule and for finalizing the Certification of Pesticide Applicators Rule.

3:00-3:15 EPA

3:15-3:45 PPDC Discussion

**3:45-4:30 6. a. Update on Dicamba Registration
b. Synergy Claims**

Session Chair: Dan Kenny, Chief, Herbicide Branch, Registration Division

Session Goal: Provide an update on the pending registration of dicamba on herbicide tolerant cotton and soybeans and discuss the implications of synergy patent claims on new registrations.

3:45-4:00 EPA

4:00-4:30 PPDC Discussion

4:30-4:45 Public Comment

4:45 Meeting Adjourns

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING – p. 3

**Lobby Level Conference Center - 2777 Crystal Drive (1 Potomac Yard South), Arlington, VA
Conference Line: 1-866-299-3188; Conference Code: 312-353-6344 #**

Thursday, November 3, 2016

9:00-10:30 7. Question and Answer Session to Topic Updates Sent in Advance of Meeting

Session Chairs: OPP Senior Leadership Team

Session Goal: Answer questions from PPDC members on:

- a. Acute 6-Pack Testing Alternatives
- b. Endangered Species Act Implementation Update
- c. Epidemiological Framework
- d. Pesticide Registration Improvement Act (PRIA) 4
- e. Resistance Management
- f. Chlorpyrifos
- g. Glyphosate

10:30-10:45 Break

10:45-11:15 8. Update from the Pesticide Incidents Workgroup

Session Chair: Jackie Mosby, Director, Field and External Affairs Division

Session Goal: Provide an update on accomplishments since May.

10:45-11:00 EPA

11:00-11:15 PPDC Discussion

11:15-11:45 9. Discussion of Agenda Topics for Next Meeting

Session Chair: Jack Housenger, Director, Office of Pesticide Programs

Session Goal: Discuss topic areas where PPDC members or OPP feels would be beneficial to have on the next agenda.

11:45-12:00 Public Comment

12:00 Meeting Adjourns

ENDANGERED SPECIES ACT (ESA) IMPLEMENTATION UPDATE

PPDC Meeting Nov. 2, 2016 – Session 7b

- Based on recommendations from the 2013 National Academy of Sciences' report "Assessing Risks to Endangered and Threatened Species from Pesticides" EPA has been working closely with the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively referred to as the Services) to develop shared interim scientific methods for use in pesticide consultations.
- EPA released draft Biological Evaluations (BEs) for three pilot chemicals including chlorpyrifos, diazinon, and malathion in April 2016. Following a 60-day public comment, EPA received over 78,600 comments with about 120 substantive comments meriting detailed review.
- In June 2016, EPA and Services held a two-day meeting that provided a forum for stakeholder suggestions for refining some of the interim scientific methods used in the April 2016 draft BEs. The meeting included opening and closing plenary sessions and breakout sessions intended to address inter-agency developed charge questions related to potential refinements for aquatic modeling, spatial and non-spatial refinements to Step 2 (i.e., EPA's determination of "likely to adversely affect" or "not likely to adversely affect"), and refinements to the weight-of-evidence (WoE) approach for plants and animals. Meeting materials including the agenda, charge questions, the opening plenary presentations, and the closing plenary reports are available at: <https://www.epa.gov/endangered-species/5th-esa-workshop-joint-interim-approaches-nas-recommendations>. EPA and the Services have reviewed the recommendations and identified those that can be addressed in the short-, mid-, and long-term.
- Recommendations from the June 2016 stakeholder meeting and public comments on the draft BEs for the three pilot chemicals will be addressed in a phased approach, given consultation deadlines and existing resources.
- In September 2016, EPA and the Services held a 3-day workshop to continue work on interim methods and tools for use in Step 3 (i.e., the Services' determination of "jeopardy/adverse modification" or "no jeopardy/no adverse modification" in the BiOp).
- Final BEs for the three pilot chemicals are expected to be released in mid-January 2017.
 - Although this date is one month later than originally anticipated, the January 2017 release of the final BEs will not impact the Services draft Biological Opinion (BiOp) deadline, given that EPA will provide the Services with any additional data needs in sufficient time for integration into the draft BiOp.
 - Expected revisions to the final BEs based on stakeholder feedback will include refined aquatic modeling, error corrections, improved transparency specifically related to the Terrestrial Effects Determination (TED) tool and the WoE matrices, and additions/deletions to the list of endangered and threatened species.
 - Other comments being considered for future BEs include: reducing the size and complexity of the BEs, moving toward more probabilistic approaches, exploring ways to better screen species with little or no risk while still being protective, refining species range maps and potential use sites, exploring use of watershed-level aquatic models, and considering the timing of potential exposure (e.g., linkage with life-history variables) and potential durations of exposure.
- Draft BEs for carbaryl and methomyl are expected to be released for public comment in the spring of 2017.
- The Services expect to release draft BiOps for the three pilot chemicals for public comment in the spring of 2017 with final BiOps by December 2017. Final BiOps for methomyl and carbaryl will be released in December 2018.

Draft “Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment”

PPDC Meeting Nov. 2, 2016 – Session 7c

In 2010, OPP developed a draft “Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment” which provides the foundation for evaluating multiple lines of scientific evidence in the context of the understanding of the adverse outcome pathway (or mode of action (U.S. EPA, 2010). The draft framework, which includes two key components: problem formulation and use of the Mode of Action/Adverse Outcome Pathway (MOA/AOP) frameworks, was reviewed favorably by the SAP in 2010 (FIFRA SAP, 2010).

OPP’s draft framework is consistent with updates to the World Health Organization/International Programme on Chemical Safety mode of action/human relevance framework, which highlight the importance of problem formulation and the need to integrate information at different levels of biological organization¹. Consistent with recommendations by the NRC in its 2009 report on *Science and Decisions*², OPP’s draft framework describes the importance of using problem formulation at the beginning of a complex scientific analysis. The problem formulation stage starts with planning dialogue with risk managers to identify goals for the analysis and possible risk management strategies. This initial dialogue provides the regulatory context for the scientific analysis and helps define the scope of such an analysis. The problem formulation stage also involves consideration of the available information regarding the pesticide use/usage, toxicological effects of concern and exposure pathways and duration along with key gaps in data or scientific information.

MOA and AOP provide important concepts in this integrative analysis. Both a MOA and an AOP are based on the premise that an adverse effect caused by exposure to a compound can be described by a series of causally linked biological key events that result in an adverse human health or ecological outcome. One of the key components of the Agency’s draft framework is the use the MOA framework /AOP concept as a tool for organizing and integrating information from different sources to inform the causal nature of links observed in both experimental and observational studies. Specifically, the modified Bradford Hill Criteria are used to evaluate the experimental support that establishes key events within a mode of action or an adverse outcome pathway, and explicitly considers such concepts as strength, consistency, dose response, temporal concordance and biological plausibility in a weight of evidence analysis.

¹ Meek ME, Boobis A, Cote I, Dellarco V, Fotakis G, Munn S, Seed J, Vickers C. 2014. New developments in the evolution and application of the WHO/IPCS framework on mode of action/species concordance analysis. [J Appl Toxicol](#). 2014 Jan;34(1):1-18.

² NRC (National Research Council). (2009). *Science and decisions: Advancing risk assessment*. Washington, DC: The National Academies Press. http://www.nap.edu/openbook.php?record_id=12209

One of the recommendations of the SAP was to gain experience integrating epidemiology and human incident information into risk assessment in order to further refine the approach in the draft framework. Consistent with this recommendation, OPP did not finalize the draft framework after the 2010 SAP but instead has used in draft framework in several chemical risk assessments (atrazine, chlorpyrifos and other organophosphates, glyphosate) to gain experience. Through this experience, OPP has refined the proposed approach with an improved, more transparent grading system for epidemiology studies; the revised framework will include this grading system.

In recent years, the [National Academies' National Research Council \(NRC\)](#) has encouraged the agency to move towards systematic review processes to enhance the transparency of scientific literature reviews that support chemical-specific risk assessments to inform regulatory decision making³. The NRC defines systematic review as "a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies". OPP has been collaborating across the other offices in the Office of Chemical Safety and Pollution Prevention (OCSPP) to implement systematic review. The concepts associated with fit-for-purpose systematic review such as standard methods for collecting, evaluating and integrating the scientific data will also be included in the revised, final framework.

OPP is actively working on revising and finalizing the draft framework and anticipates release of the final document within the next few months.

³ NRC 2011. "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde"; NRC 2014. "Review of EPA's Integrated Risk Information System (IRIS) Process"

Draft “Framework for Incorporating Human Epidemiologic & Incident Data in Health Risk Assessment”

PPDC Meeting Nov. 2, 2016 – Session 7c

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¹ [Meek ME](#), [Boobis A](#), [Cote I](#), [Dellarco V](#), [Fotakis G](#), [Munn S](#), [Seed J](#), [Vickers C](#). 2014. New developments in the evolution and application of the WHO/IPCS framework on mode of action/species concordance analysis. [J Appl Toxicol](#). 2014 Jan;34(1):1-18.

² NRC (National Research Council). (2009). *Science and decisions: Advancing risk assessment*. Washington, DC: The National Academies Press. http://www.nap.edu/openbook.php?record_id=12209

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³ NRC 2011. "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde"; NRC 2014. "Review of EPA's Integrated Risk Information System (IRIS) Process"

Update on Changes to Maintenance Fees and PRIA 4 PPDC Meeting Nov. 2, 2016 – Session 7d

[These bullets reflect the status of PRIA 4 while we were providing technical advice to the PRIA Stakeholder Coalition during development, but we have not seen the actual Bill language being developed by Congress.]

Maintenance Fees

- Extends fees for 7 more years from FY'17 thru FY'23;
- Fees increased from \$27.8M to \$31.0M per year;
- Can average across years to correct for over or under collection in previous years during PRIA 4;
- Eliminates IT set-aside (\$800,000 per year) to improve (a) electronic tracking of registration submissions, (b) electronic tracking of conditional registrations, (c) electronic review of labels, (d) electronic CSFs and (e) ESA database enhancements (but reporting on the unspent balance of PRIA 3 IT set-asides remains);
- Creates new \$500,000 per year set-aside to support efficacy guideline development and rulemaking for invertebrate pests of significant public health and/or economic importance with a mandatory schedule of deliverables;
- Creates new \$500,000 per year set-aside to support GLP inspections;

PRIA 4 (Pesticide Registration Enhancement Act of 2016)

- Extends PRIA for 7 more years from FY'17 thru FY'23;
- Increases the number of covered fee categories from 189 to 212; changes include but not limited to:
 - adds harmonization with Codex MRLs to existing category;
 - adds categories for pests requiring efficacy data and review;
 - adds new EUP categories for AD, BPPD and RD chemicals;
 - AD categories modified to be consistent with 158W;
 - adds unregistered source of AI category for BPPD;
 - adds new PIP categories;

- adds new inert safener categories and lengthens certain inert category timeframes where warranted by their average completion times and the # of renegotiations;
- Enhances incentives for reduced-risk submissions by raising fees for the corresponding non-reduced risk categories (new conventional AIs and new uses);
- Eliminates small business waivers for Gold Seal letters;
- New reporting requirements:
 - identify reforms to streamline new AI and new use processes and provide prompt feedback to applicants during the process;
 - progress in meeting mandatory schedule in developing efficacy guidelines for invertebrate pests of significant public health and/or economic importance;
 - # of GLP inspections/audits conducted;
 - progress in priority review and approval of new pesticides to control vector borne pests in the U.S. including territories and military bases globally;
 - # of registration review cases completed, fully implemented, required mitigation
- Updates Section 5 on EUPs to be consistent with PRIA 4 timeframes.

EPA's Pesticide Registration Notices (PRNs) on Resistance Management PPDC Meeting Nov. 2, 2016 – Session 7e

Background

Many pesticides have gradually lost their effectiveness over time because pests have developed resistance, a significant decrease in sensitivity to a pesticide, which reduces the field performance of these pesticides. The agency is concerned about resistance issues and believes that managing the development of pesticide resistance, in conjunction with alternative pest-management strategies and Integrated Pest Management (IPM) programs, is an important part of sustainable pest management. To address the growing issue of resistance and prolong the useful life of pesticides, the agency has initiated a more widespread effort that is aimed at combating and slowing the development of pesticide resistance. On June 3, 2016, the agency concurrently released and requested public comment on two draft Pesticide Registration Notices (PRNs) related to pesticide resistance. The public comment closed on September 1, 2016. The two PRNs include:

1. PRN 2016-X: Draft Guidance for Pesticide Registrants on Pesticide Resistance Management Labeling. PRN 2016-X revises and updates PRN 2001-5, which is the agency's current guidance for pesticide resistance management labeling. This PRN applies to all agricultural pesticides except plant-incorporated protectants (PIPs), which are covered by a separate guidance issued by the Biopesticides and Pollution Prevention Division (BPPD). The updates in PRN 2016-X focus on pesticide labels and are aimed at improving information about how pesticide users can minimize and manage pest resistance.
2. PRN 2016-XX: Draft Guidance for Pesticide Registrants on Herbicide Resistance Management Labeling, Education, Training, and Stewardship. PRN 2016-XX applies only to herbicides. This PRN communicates the Agency's current thinking and proposes an approach to address herbicide-resistant weeds by providing guidance on labeling, education, training, and stewardship for herbicides undergoing registration review or registration. It is part of a holistic, proactive approach to slow the development and spread of herbicide-resistant weeds, and to prolong the useful lifespan of herbicides and related technology. The Agency is focusing on guidance for herbicides first because they are the most widely used agricultural chemicals, no new herbicide mechanism of action has been developed in the last 30 years, and the number of herbicide-resistant weed species and acres infested with resistant weeds have increased rapidly in recent years.

Current Status

The Agency is in the process of reviewing and addressing the public comments we received on these PRNs.

1. The Agency received 19 comment letters on the pesticide labeling PRN (2016-X) from non-governmental organizations (NGOs), grower groups, professional scientific societies, registrants, resistance action committees (RACs), and USDA. The main themes included the following:
 - A. General agreement that additional information on resistance management on labels would be useful – especially the routine inclusion of a pesticide’s Mode of Action group as set by the various RACs.
 - B. A few RACs disagreed with some of the suggested label statements in the guidance, particularly for fungicides and insecticides. EPA is in the process of evaluating if and how these label statements should be altered based on these comments.
 - C. Some commenters expressed concern and confusion on: (1) whether non-agricultural pesticides are covered and (2) whether all of the guidance in this PRN is mandatory for registrants or pesticide users. EPA is in the process of reviewing these comments and will clarify these issues in the final version of the PRN.
2. The Agency received 27 comment letters on the herbicide resistance management PRN (2016-XX) from NGOs, crop groups, professional societies, registrants, RACs, and USDA. The main themes included the following:
 - A. General agreement that pesticide labels should provide additional resistance management information. A few commenters, however, did not agree that extensive resistance management language is appropriate for labels.
 - B. The Agency proposed three categories of concern (low, medium, high) based on the potential for weeds to develop herbicide resistance. The three categories proposed different approaches for resistance management in regards to labeling, education, training, and stewardship guidance. Most commenters recommended that all herbicides be grouped into a single category and treated as if there is high concern for resistance.
 - C. Many commenters were against having the registrants provide additional information to the user/grower (e.g. a separate lists of resistant weeds, additional reporting of resistant weeds, or resistance management plans).

Next Steps

The Agency is evaluating the public comments and expects to finalize both PRNs in late 2016. Also, the Agency plans to implement herbicide resistance measures for existing chemicals during registration review, and to implement herbicide resistance measures for new herbicides and new uses at the time of registration.

Chlorpyrifos Status Update for
PPDC Meeting Nov. 2, 2016 – Session 7f
Prepared: October 19, 2016

Background

The EPA must respond to a National Resources Defense Council (NRDC) and Pesticide Action Network of North America (PANNA) petition seeking the revocation of all chlorpyrifos tolerances and cancelation of all registrations for chlorpyrifos, citing human health concerns. In October 2015, the EPA issued a proposed tolerance revocation for chlorpyrifos based on the science as it stood. There are several unresolved scientific issues the EPA has been working through before issuing a final decision.

EPA has considered several approaches in determining the critical effect, and related uncertainties, for use in the chlorpyrifos human health risk assessment. The 2014 revised human health risk assessment used dose-response data on acetylcholinesterase inhibition (AChI) in laboratory animals to derive a point of departure. However, the EPA believes that evidence from epidemiology studies indicates effects may occur at lower exposures than indicated by the toxicology database. The EPA consulted with the FIFRA Scientific Advisory Panel (SAP) on using a specific epidemiology study to establish a new toxicological endpoint and associated point of departure for the chlorpyrifos risk assessment. The SAP advised against that approach. The SAP also emphasized concern that the point of departure based on AChI is not sufficiently health protective for use in risk assessment. The 2016 SAP cited that epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below these levels, which is consistent with recommendations from the 2012 SAP meeting on chlorpyrifos.

The EPA has thoroughly considered the SAP's recommendations, and is currently finalizing its 2016 revised risk assessment. The EPA anticipates making the revised risk assessment, along with an updated drinking water assessment, available for public comment in the very near future. The EPA anticipates issuing a final tolerance rule for chlorpyrifos by the court-ordered deadline, March 31, 2017.

Milestones

- The EPA anticipates issuing a Notice of Data Availability (NODA) for the proposed rule in the very near future. The NODA will include a revised human health risk assessment, updated drinking water assessment, and other supporting information. The EPA will also notify the World Trade Organization of EPA's impending tolerance decision at this time.
- The Notice of Data Availability will be published for a 60-day public comment period.
- The EPA will respond to public comments and finalize its decision on the chlorpyrifos tolerance rule by March 31, 2017.

Glyphosate Update

PPDC Meeting Nov. 2, 2016 – Session 7g

Overview

Glyphosate is a non-selective, phosphonomethyl amino acid herbicide registered to control weeds in various agricultural and non-agricultural settings. Labeled uses of glyphosate include over 100 terrestrial food crops as well as other non-agricultural sites, such as greenhouses, aquatic areas, and residential areas. Use of glyphosate in the United States and globally has increased overtime, particularly with the introduction of glyphosate-resistant crops; however, usage has stabilized in recent years due to the increased number of weed species becoming resistant to glyphosate. Glyphosate is currently undergoing Registration Review, which reviews all registered pesticides at least every 15 years as mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Recently, EPA collected and analyzed a substantial amount of data informing the carcinogenic potential of glyphosate and utilized the draft “Framework for Incorporating Human Epidemiological & Incident Data in Health Risk Assessment”, which provides the foundation for evaluating multiple lines of scientific evidence. A comprehensive analysis of data on glyphosate from submitted guideline studies and the open literature was performed. This includes epidemiological, animal carcinogenicity, genotoxicity, and absorption, distribution, metabolism, and excretion (ADME) studies. Guideline studies were collected for consideration from the toxicological databases for glyphosate and glyphosate salts. A fit-for-purpose systematic review was executed to obtain relevant and appropriate guideline and open literature studies with the potential to inform the human carcinogenic potential of glyphosate. Furthermore, the list of studies obtained from the toxicological databases and systematic review was cross-referenced with recent internal reviews, review articles from the open literature, and international agency evaluations.

Available data from epidemiological, animal carcinogenicity, and genotoxicity studies were reviewed and evaluated for study quality and results to inform the human carcinogenic potential of glyphosate according to the 2005 Guidelines for Carcinogen Risk Assessment. A total of 58 epidemiological studies, 20 animal carcinogenicity studies, and almost 200 genotoxicity assays were considered in the current evaluation. Additionally, multiple lines of evidence were integrated in a weight-of-evidence analysis using the modified Bradford Hill Criteria considering concepts, such as strength, consistency, dose response, temporal concordance, and biological plausibility. The totality of the data has been used by the agency to inform cancer classification descriptors according to the 2005 Guidelines for Carcinogen Risk Assessment. The agency originally planned to hold the FIFRA Scientific Advisory Panel (SAP) evaluation of human carcinogenic potential for the active ingredient glyphosate on October 18-21, 2016.

On October 14, 2016, EPA postponed the FIFRA SAP meeting due to recent changes in the availability of experts for the peer review panel. Given the importance of epidemiology in the review of glyphosate’s carcinogenic potential, the agency believes that additional expertise in epidemiology will benefit the panel and allow for a more robust review of the data. As a result, the SAP meeting on glyphosate has been postponed. The agency will issue another announcement once the new date for the SAP meeting on glyphosate has been determined.

From: Kunickis, Sheryl - OSEC
To: [Mueller, Rick - NASS](#); [Chin, Teung](#); [Schroeder, Jill](#); [Epstein, David](#); [Fajardo, Julius](#); [Domesle, Alexander - ARS](#)
Subject: FW: June ESA stakeholder workshop: complete meeting materials
Date: Tuesday, June 28, 2016 3:58:18 PM
Attachments: [workshop reading materials.final.docx](#)
[WOE charge questions.final.docx](#)
[aquatic modeling charge questions.final.docx](#)
[refinements charge questions.final.docx](#)
[workshop final agenda.docx](#)
[Capel et al 2001.pdf](#)

See attached as they are the final versions – fyi.

From: Nguyen, Khue [mailto:Nguyen.Khue@epa.gov]
Sent: Monday, June 27, 2016 11:32 AM
To: Patrice Ashfield; craig_aubrey@fws.gov; Cowles, James; Brett Hartl; Kunickis, Sheryl - OSEC; Pease, Anita; Ben Sacher; cathy.tortorici@noaa.gov
Cc: Bernalyn McGaughey; Francesca Purcell
Subject: June ESA stakeholder workshop: complete meeting materials

Hi all,

I am forwarding to the workshop “floaters” the complete meeting materials for the June ESA stakeholder workshop, which includes the final agenda, the charge questions for each breakout group, and the list of reading materials.

See you all at the workshop on Wednesday!

Thanks,

Khue Nguyen
Chemical Review Manager
Risk Management and Implementation Branch 1
Pesticide Re-evaluation Division
Office of Pesticide Programs, EPA
703-347-0248
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ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016)
RECOMMENDED READING MATERIALS

Materials to read prior to the workshop All of the draft biological evaluation documents can be accessed from the following EPA website (Implementing NAS Report Recommendations on Ecological Risk Assessment for Endangered and Threatened Species): <https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and>.

All Breakout Sessions:

- The NAS Report (Assessing Risk to Endangered and Threatened Species from Pesticides): General Conclusions and Recommendations (pages 33-34)
- Relevant sections of EPA OPP Ecological Risk Assessment for Pesticides (<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/ecological-risk-assessment-pesticides-technical>)
- For an understanding of ESA Consultation, <https://www.fws.gov/endangered/what-we-do/faq.html#9>

Breakout Session: Improving Aquatic Modeling: Changes to conceptual and mathematical approaches incorporated into Bins 3 and 4 (flowing waters) and Evaluating watershed model results

Both aquatic modeling breakout groups:

- **Attachment 3-1**, Background document: Aquatic Exposure Estimation for Endangered Species
- The NAS Report (Assessing Risk to Endangered and Threatened Species from Pesticides): **Section 3**
- Capel et al. 2001. The behavior of 39 pesticides in surface waters as a function of scale. Hyrol. Process. (15) 1251-1269 (see attached).

Breakout Session: Refinements to Steps 1 and 2: (Ideas for ‘streamlining’ and/or improving the analyses used to make effects determinations in future BEs):

Breakout Group: REFINEMENTS 1 (Refinements to Steps 1 and 2: Spatial analysis):

- Draft Chlorpyrifos Problem Formulation for ESA Assessment (**Chapter 1**) – especially section 1.4.1
- **Attachment 1-2** – CDL Crosswalk
- **Attachment 1-3** – Method for Establishing the Use Footprint
- **Attachment 1-6** – Co-Occurrence Analysis
- **Appendix 1-6** – Use Site, General Land Cover Class, and HUC2 Matrix for Chlorpyrifos
- Draft Chlorpyrifos Effects Determinations for ESA Assessment (**Chapter 4**) – especially sections 2, 3, and 4
- **Appendix 4-7** – Refined Risk Analyses for 11 Listed Birds Exposed to Diazinon – especially section 4

- **Appendix 4-7-supp-2** – GAP Land covers assigned as preferred habitats (diazinon)
- **NAS Report** (2013; *Assessing Risk to Endangered and Threatened Species from Pesticides*): Geospatial Data for Habitat Delineation and Exposure Modeling, pages 41-48; Section 3 Conclusions and Recommendations, pages 58-59

Breakout Group: REFINEMENTS 2 (Refinements to Steps 1 and 2: Non-spatial analysis):

- Draft Chlorpyrifos Problem Formulation for ESA Assessment (**Chapter 1**) – for question 3b, especially sections 1.4.1 and 1.4.2
- Draft Chlorpyrifos Effects Determinations for ESA Assessment (**Chapter 4**) – especially sections 7-2 and 7-3
- **Attachment 1-4** – Process for Determining Effects Thresholds
- **Attachment 1-5** - Method for Deriving Species Sensitivity Distributions for Use in Pesticide Effects Determinations for Listed Species
- **Attachment 1-7** – Methodology for Estimating Exposures to Terrestrial Animals
- **Attachment 3-1** – Background Document: Aquatic Exposure Estimation for Endangered Species
- **NAS Report** (2013; *Assessing Risks to Endangered and Threatened Species from Pesticides*) – especially Chapter 5
- Draft Chlorpyrifos Effects Characterization for ESA Assessment **Chapter 2**

Breakout Sessions: Weight of Evidence for Listed Animals and Plants

Both Weight of Evidence breakout groups (animals and plants):

- Draft Chlorpyrifos Problem Formulation for ESA Assessment (**Chapter 1**) – especially section 1.4.2
- **Attachment 1-4** – Process for Determining Effects Thresholds
- **Attachment 1-5** – Method for Deriving Species Sensitivity Distributions for Use in Pesticide Effects Determinations for Listed Species
- **Attachment 1-7** – Method for Estimating Exposure to Terrestrial Animals
- **Attachment 1-8** – Review of Open Literature Toxicity Studies for Pilot Chemical Biological Evaluations
- **Attachment 1-9** – Applying a Weight-of-Evidence Approach to Support Step 2 Effect Determinations, i.e., Not Likely to Adversely Affect (NLAA) or Likely to Adversely Affect (LAA)
- **Attachments 1-11 through 1-21** – Biological Information on Listed Species
- **Attachment 3-1** – Background Document: Aquatic Exposure Estimation for Endangered Species
- **NAS Report** (2013; *Assessing Risks to Endangered and Threatened Species from Pesticides*) – especially the Chapter 2 section on Best Data Available (beginning on page 39), Chapters 3 and 4 sections on uncertainties, and Chapter 5 section on probabilistic approach
- Draft Chlorpyrifos Effects Characterization for ESA Assessment (**Chapter 2**)
 - Draft Chlorpyrifos Exposure Characterization for ESA Assessment (**Chapter 3**)

Supplemental reading materials for both WOE Groups:

- As referenced by the NAS Panel report:
 - Exponent (Bellevue, Washington), for Science Advisory Board for Contaminated Sites in British Columbia. *Guidance for a weight of evidence approach in conducting detailed ecological risk assessments (DERA) in British Columbia*. Prepared for the British Columbia

Ministry of Environment, June 2010 (Available here:
<http://www.sabcs.chem.uvic.ca/a%20January%202011%20Posting%20copy%20Weight%20of%20Evidence%20Final%201.pdf>)

- Igor Linkov, Drew Loney, Susan Cormier, F. Kyle Satterstrom and Todd Bridges. *Review: Weight-of-evidence evaluation in environmental assessment: Review of qualitative and quantitative approaches*. Science of the Total Environment 407: 5199–5205, 2009. (Available at no cost from Google Scholar)
- Additional suggestion:
 - Bruce K. Hope and Jacquelyn R. Clarkson. A strategy for using weight-of-evidence methods in ecological risk assessments. Human and Ecological Risk Assessment 20: 290–315, 2014. (Copyrighted)

ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016):

Breakout Sessions WOE 1 and WOE 2: Weight of Evidence for Listed Animals and Plants

The draft biological evaluations for chlorpyrifos, diazinon and malathion rely upon a weight of evidence (WoE) approach to make species-specific effects determinations. Risk conclusions are based on the integration of exposure and effects information relevant to an individual of a listed species, as well as life history characteristics that may influence exposure or indirect effects (e.g., diet). Different types of effects are identified in this approach as separate lines of evidence; including: mortality, growth, reproduction, behavior, sensory effects and indirect effects. Additionally, other factors that could affect the magnitude of both direct and indirect effects (e.g., chemical or abiotic stressors) are evaluated as lines of evidence. Weighting is applied to each line of evidence and the weighting criteria provide guidelines for supporting effects determinations based on the pairings of risk and confidence. The current weighting criteria are defined in Attachment 1-9.

An effort was made to incorporate and evaluate as much toxicity and exposure data as possible to determine whether adverse effects are anticipated from the effects of the action. Both the toxicity and exposure information are evaluated to determine the risk and confidence associated with each line of evidence. Currently, the process uses numeric thresholds to determine risk. EPA and the services have discussed integrating distributions of effects and exposures to move towards a more probabilistic approach (e.g., such as the method used in the Terrestrial Investigation Model); however, this is seen as more of a long term goal for application to all species. EPA and the Services are interested in suggestions that improve the WoE method. When addressing the questions below, answers will be grouped into “short term” or “long term” solutions, considering the magnitude of work associated with developing and applying the methods to all listed species (n ≈ 1800).

The same set of questions will be considered by the WoE groups focused on plants and on animals; however, the discussions are expected to differ. For instance, issues related to exposure differ between animals and plants in that the routes and models are conceptually and mathematically different. For effects, data are available for multiple lines of evidence for assessing direct effects to animals (i.e., mortality, growth, reproduction, behavior and sensory); whereas mortality, growth and reproduction data are only available for plants. It is expected that discussions related to animals will likely surround the topics of assessing direct effects to listed individuals as well as indirect effects due to impacts on animals and plants. For plants, discussions should probably focus more on indirect effects due to impacts to animals upon which they depend (e.g., for pollination or seed dispersal).

- **Exposure Information-** Criteria used to assess exposure estimates ultimately answer the question, “how confident are we that exposure estimates represent environmental concentrations that could occur based on allowable labeled use?” The current approach for characterizing exposure considers the relevance of predicted EECs for species’ habitats and the robustness of EECs derived from environmental fate models (see Attachment 1-9 for more details). Considering the current approach to characterizing exposure:
 - **CHARGE QUESTION 1:** Comment on/suggest alternative methods for presenting exposure information (e.g., probability distributions, consideration of a range of exposure estimates, consideration of duration of exposure) and how the information can be weighed for each line of evidence’s risk conclusion.
 - **CHARGE QUESTION 2:** Comment on the criteria used to weight Confidence in the estimation of exposure as described in Supplemental Information to Attachment 1-9.

- **Effects Information**- Similar to the exposure characterization, the effects data are evaluated to answer the question, “how confident are we that available toxicity data will accurately predict an effect to the listed species?” The current approach considers 1) biological relevance- whether there is an established relationship between the measure of effect and the assessment endpoint, 2) relevance of surrogate- how representative the tested organisms used in the toxicity studies are at informing the potential for adverse effects to listed species or critical habitat, and 3) robustness- whether there is consistency within the line of evidence for the taxonomic grouping of interest (see Attachment 1-9 for more details). Considering the current approach to characterizing effects:
 - **CHARGE QUESTION 3:** Comment on approaches for incorporating data quality into the weight assigned to a line of evidence. The current approach to data quality is described in Attachment 1-8.
 - **CHARGE QUESTION 4a:** For animals, to what extent can taxa with robust data sets be used as surrogates for other taxonomic groupings where lines of evidence have little or no data (*e.g.*, mammals for reptiles)?
 - **CHARGE QUESTION 4b:** For plants, comment on the approach to surrogacy. Is there a better or more representative way to group species?
 - **CHARGE QUESTION 5:** How can we more effectively incorporate the breadth of the available toxicity information (*i.e.*, not just the most sensitive endpoints), including magnitude of effect, into the characterization of effects and weight of evidence?
 - **CHARGE QUESTION 6:** How can we effectively weigh the impacts of other stressors (*e.g.*, temperature) on the LAA/NLAA call, especially in the event of little or no data?
 - **CHARGE QUESTION 7:** Are there additional sublethal effects that have an established relationship with an assessment endpoint that should be considered as lines of evidence?
 - **CHARGE QUESTION 8:** Comment on the criteria used to weight Confidence in the estimation of effects as described in Supplemental Information to Attachment 1-9.

- **Risk Estimation**- Risk is established by comparing the overlap of exposure with effect levels from available toxicity studies for each line of evidence. Consideration is given to the degree of overlap between exposure and effects data. Considering the current approach to estimating risk:
 - **CHARGE QUESTION 9:** Comment on the criteria used to weight Risk as described in Supplemental Information to Attachment 1-9.

ESA STAKEHOLDER WORKSHOP (JUNE 29-30, 2016):

Breakout Sessions: Improving Aquatic Modeling

Breakout Session AQUATIC 1: Changes to Conceptual Models and Mathematical Approaches Incorporated into Bins 3 and 4 (Flowing Waters):

In the draft Biological Evaluations (BEs), effect determinations are made at the individual scale of biological organization. Consequently, the goal is to accurately predict maximum pesticide concentrations that may occur in different aquatic habitats utilized by listed species and are spatially and temporally relevant to the listed species. The modeling approach presented in the draft BEs leveraged EPA's current generic aquatic modeling approach by using the Pesticide in Water Calculator (PWC) shell, a combination of field-scale models (PRZM5/VVWM), to generate estimated exposure concentrations (EECs) for three generic flowing water bins of varying volumes and flow rates (Bins 2, 3, and 4). The Bin 2 estimates are intended to represent lower-flow habitats, such as first-order streams. When considered in relation to field-scale monitoring data, such as those obtained from edge-of-field (EOF) studies, model results should provide confidence in EECs for this bin. There is expected to be less confidence in applying this approach for deriving estimates for Bins 3 and 4, because processes that affect larger-scale concentration dynamics (*e.g.*, longitudinal dispersion) are not accounted for. The EECs derived for these higher-flow habitats in the draft BEs are extremely high and seem to defy both professional judgement and typical patterns seen in contaminant monitoring data.

In the context of watershed hydrodynamics, the three flowing bins represent aquatic habitats which would ideally be representative, for example, of streams that are sequentially connected within a watershed. While runoff and drift from a field adjacent to a Bin 3 and/or 4 waterbody can directly contribute loading, the EECs generated from these types of events are being characterized with Bin 2 EECs, as these EECs may be reflective of concentrations occurring before complete mixing within the Bin 3 and/or 4 waterbody had occurred. Initial modeling generated Bin 3 and 4 EECs that exceed those generated for Bin 2, which runs counter to expectations based on standard transport dynamics, *e.g.*, dispersive dampening of chemographic peak maxima as a pulse of contaminant moves downstream. Given the apparently unreasonably high EECs for Bins 3 and 4, a qualitative approach was considered in the draft BEs for use in assessing these bins. The approach relied on monitoring data to demonstrate a downward trend in the magnitude of peak exposures. Consistent with published studies showing a reduction in exposures as one moves down a watershed network, the approach showed a 5-fold reduction in exposure from Bin 3-like streams and a 10-fold reduction from Bin 3-like streams to Bin 4-like streams. The draft BE also applied a qualitative comparison of volumes and flowrates to suggest a reasonably conservative magnitude of exposure expected in Bins 3 and 4 as a separate line of evidence.

Charge Questions:

1. EPA explored several factors in using the PWC, including incorporation of a baseflow and use of the daily average instead of the instantaneous peak EEC. What are the strengths and weaknesses of these modifications? Are there other modifications that can be made and what are their strengths and weaknesses?
2. How appropriate are the methods used in the draft BEs to develop field/watershed sizes and waterbody lengths for these Bins? What reasonable alternatives could be used to model

watershed processes that allow for accurate estimation of possible exposure concentrations (including the maximum) in these flowing bins based on product labeling?

3. For the bins (3 and 4) that represent larger flowing systems, what ways of incorporating the effects of dispersive mixing and/or peak desynchronization into concentration estimates are reasonable?
4. What are the strengths and weaknesses of alternative mechanistic or regression-based watershed models such as the Soil and Watershed Assessment Tool (SWAT), the Hydrological Simulation Program-Fortran (HSPF) and the Watershed Regressions for Pesticides (WARP) for simulating aquatic pesticide concentrations at the temporal resolution and national scales required for ESA assessment? Are there other watershed models that should be considered?
5. What is the desired and appropriate spatial scale for EECs for Bins 3 and 4? Specific PWC EECs were developed for HUC2 regions. Can or should the EECs for Bins 3 and 4 be at a finer spatial scale given a nationwide consultation?

Breakout Session AQUATIC 2: Evaluating Watershed Model Results:

In the Draft BEs, EPA employed an approach for flowing waters in an effort to approximate watershed processes. Regardless of the model employed, the EECs from any model need to be conservative (*i.e.*, protective of the species of concern) and scientifically defensible in order to be used for risk assessment purposes. Typically, for EPA's use of PRZM5/VVWM as a field-scale model for vulnerable waters (*e.g.*, headwater streams), this would be done by comparing model outputs to field monitoring data (*i.e.*, edge of field runoff studies), where pesticide monitoring data is associated with pesticide-applications under well-described conditions (*i.e.*, application rates, field characteristics, water characteristics, and meteorological conditions). However, for watershed modeling, which aggregates exposure across a larger area, field-scale monitoring data, and the associated well-described conditions for all locations in the watershed, can be extremely difficult to obtain and, as a watershed model aggregates exposure, it may not be necessary.

Available literature documents have evaluated watershed models, including the NAS-recommended model SWAT, using general and targeted watershed monitoring data that is focused on known high pesticide-use areas, provided the data are collected at a high enough frequency to adequately capture the peak exposure concentration along with variations in concentration in the receiving stream. Unlike field monitoring data, general monitoring data (*i.e.*, sometimes described as ambient monitoring data) often lacks background information on application rates and field conditions and can be problematic when used for comparisons to model-generated EECs. They may, however, provide a lower bound for model-generated EECs. Targeted watershed monitoring (*e.g.*, studies at a watershed scale that are targeted to areas of known high pesticide use, with a sampling frequency targeted to the timing of use and subsequent runoff events) has been proposed as a means to provide more than a lower bound, especially when such monitoring spans multiple years and can be tied to factors that drive pesticide transport from field to water bodies. Such data are used to complement the results from modeling, not as a substitute for modeling.

In the Exposure chapter of the 2013 NAS report¹, the NAS noted that "If pesticides are to be used without jeopardizing the survival of listed species and their habitats, the estimated environmental concentrations (EECs) to which the organisms and their habitats will be exposed need to be determined. Chemical fate and transport models are the chief tools used to accomplish that task." (p. 49) The NAS further went on to describe a stepwise approach to fate and transport modeling, commenting on the use of various models such as AgDRIFT, PRZM, and EXAMS (p. 52-54). The NAS then cautioned that "in evaluating models, general monitoring data and field studies need to be distinguished. General monitoring studies provide information on pesticide concentrations in surface water or ground water on the basis of monitoring of specific locations at specific times. The monitoring reports, however, are not associated with specific applications of pesticides under well-described conditions, such as application rate, field characteristics, water characteristics, and meteorological conditions. General monitoring data cannot be used to estimate pesticide concentrations after a pesticide application or to evaluate the performance of fate and transport models." (p. 54) Though not as abundant as general monitoring data, field-scale monitoring studies are available for many pesticides, including the three OPs. However, monitoring data with this type of supporting information are generally lacking at the watershed scale.

¹ National Academy of Sciences. 2013. Assessing Risks to Endangered and Threatened Species from Pesticides. The National Academies Press. Washington, DC.

Additionally, the general monitoring data, specifically at the watershed scale, sometimes include data sets which are spatially and temporally targeted to varying degrees with pesticide applications. Lastly, the NAS noted that “pesticide fate and transport models do not provide information on the watershed scale; they are intended only to predict pesticide concentrations in bodies of water at the edge of a field on which a pesticide was applied.” (p. 54) The NAS also noted that “different hydrodynamic models are required to predict how pesticide loadings immediately below a field are propagated through a watershed or how inputs from multiple fields (or multiple applications) aggregate throughout a watershed.” The NAS report did not provide additional discussion on the monitoring data requirements (*e.g.*, metadata such as use rates, location, and timing) needed to evaluate watershed models.

Given the distinctions above between field-scale and watershed-scale models, the question arises “how does one evaluate the results generated from a watershed model?” EPA is proposing to use of the following multiple lines of evidence to evaluate the range of scientifically-defensible EECs for each flowing bin: consideration of available edge-of-field monitoring data and edge-of-field modeled estimates from PRZM5; incorporation of results from multiple watershed models, as appropriate; and consideration of statistical approaches to estimate confidence bounds around general monitoring data that were collected at a greater than a daily time step (*i.e.*, SEAWAVE Q and bias factors).

Charge Questions:

1. In what ways are a “multiple lines of evidence” approach appropriate for evaluating the results from a watershed model? What would be the “lines of evidence” and sources of information?
2. How can different types of monitoring data be distinguished? What metadata requirements (*e.g.*, use info, sample frequency, etc.) can be used to distinguish types of monitoring data?
3. What roles can the various types of monitoring data play in the evaluation of results from a watershed model (*e.g.*, general monitoring doesn’t predict maximum but has other roles)?
4. What other approaches are available for evaluating results from watershed models?
5. To what extent can we rely on historical monitoring data when product labeling has changed and application-specific information is lacking?
6. Are there new or different types of monitoring that could be employed to further our understanding of aquatic modeling estimates?

ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016):

Breakout Session: Refinements to Steps 1 and 2 (Ideas for ‘streamlining’ and/or improving the analyses used to make effects determinations in future BEs)

In accordance with the Endangered Species Act (ESA), the Biological Evaluation (BE) determines whether there is a potential for a single individual of a listed species, or its designated critical habitat, to be adversely affected (directly or indirectly) by a federal agency’s proposed action (in this case registering pesticide labels). This is accomplished by first identifying which species ranges/critical habitats overlap with the ‘action area’¹ (from the BE Step 1: ‘May Affect’/‘No Effect’ determinations). Once a determination is made for each listed species and critical habitat, species- and critical habitat-specific analyses for all listed resources that have ‘May Affect’ determinations are conducted to evaluate whether there is a potential for a single individual (or essential critical habitat feature) to be adversely affected² by the use of a pesticide (BE Step 2: ‘Likely to Adversely Affect’/‘Not Likely to Adversely Affect’ determinations). Therefore, Step 1 is intended to identify those species/critical habitats that require species-specific analyses (*i.e.*, those that need to proceed to Step 2) and Step 2 is intended to identify the potential for adversely affecting a single individual or critical habitat feature. Key to these processes is the ability to identify areas of overlap among potential use sites, areas of potential effects, and species range/critical habitat areas over the duration of the proposed action (in some cases this may be 15 years or more).

- **Breakout Group: REFINEMENTS 1 (Refinements to Steps 1 and 2: Spatial analysis):**
 - o For agricultural uses, the interim process identifies potential use sites by collapsing >100 Cropland Data Layer (CDL) classes into 11 agricultural use categories, some of which are unambiguous major crops (corn, cotton, *etc.*), and some of which are aggregated “minor” crops, *e.g.*, orchards and vineyards, or ground fruit and vegetables. (These minor crops were aggregated to address uncertainties in crop identification in the CDL, and to anticipate future use areas for pesticides, based on current uses.) Therefore, in some cases, specific crop uses are being identified in areas where the specific crop likely does not occur. For example, the orchard-vineyard layer is used for all orchard crops, including citrus. Diazinon is registered for some orchard crops, but not citrus – the spatial analysis is showing orchard use sites for diazinon in Florida – but most of those use sites are likely citrus.

¹ The action area is defined by statute as all areas to be affected directly or indirectly by the Federal Action and not merely the immediate area involved in the Action (50 CFR 402.02). The action area is, thus, related to the proposed action and is independent of the geographic area in which listed resources occur.

² Adverse effects to an individual are not limited to mortality, and include short-term and temporary effects (from direct and/or indirect effects) to individuals. Step 2 analyses do not evaluate the potential for “jeopardy” or “adverse destruction/modification” for species and critical habitat, respectively. Such an analysis would be conducted in Step 3 in a Biological Opinion.

- **CHARGE QUESTION 1a: Is there a better way to accurately identify potential agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?**
 - Are there some CDL classes that we have more confidence in than others?
 - Is using the Census of Agriculture to eliminate counties where labeled uses do not occur a viable option for both current uses and future uses (within the duration of the proposed action)? If so,
 - How should we deal with “undisclosed” census values?
 - Do these data (or other suitable data) reflect “no usage” or “low” levels of usage over the duration of the proposed action?
- Non-agricultural label uses include a wide range of land cover and land use categories. In the BEs, each label use is considered and represented by the best available land cover data. Generally, the National Land Cover Dataset (NLCD) is used to represent non-agricultural label uses. When the NLCD is inadequate, other data sources are used as appropriate.
- **CHARGE QUESTION 2a: Is there a better way to accurately identify potential non-agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?**
 - Are there additional data not considered in the BEs that may be useful for geographically identifying non-agricultural use sites?
 - Are there surrogate data (those that could be used to help inform potential use sites) that could be used for non-ag categories that we have not considered?
- Some uses do not have clear geographic boundaries (*i.e.*, they are difficult to limit geographically via label language). For some chemicals, this can result in an action area that encompasses the entire US and its territories.
- **CHARGE QUESTION 3a: How can we better identify potential use sites for pesticide uses that do not have clear geographic boundaries? How could these potential use sites be better identified spatially?**
 - Could a process to modify labels (to clarify potential use sites) be developed during the BE process? If so, what would that process look like?
 - For example, when in the BE process would label clarifications be most useful? Could label modifications be in the form of a registrant commitment to modify a label as part of the final decision? How could Bulletins Live Two be best used in the process?

- For uses such as mosquito adulticide use, what other information could be pulled in to the analyses to help accurately limit the spatial extent (for example census information, or protected/managed lands) for the duration of the proposed action? Is there a human population density threshold where the cost of applying a pesticide would be too high?
 - If it is not possible to geographically define a use site, can we geographically define where the pesticide isn't (or won't be) applied that would provide spatial refinement (*i.e.*, it will not be applied to open water, or urban areas, *etc.*).
- The range data currently available for listed species are geospatially represented using polygons and they are used in the BEs with the assumption that the species use all areas of their polygon equally throughout the year.
 - **CHARGE QUESTION 4a: Are there methods available that would allow for a refined understanding of the distribution of individuals within the range polygons?**
 - Are there methods that can be used to help identify areas of concern within a species' range to better estimate the likelihood of exposure – preferred habitat, distribution of individuals (do they cluster, are they territorial, min patches requirements for a home range, fragmentation indices)?
 - Is there biological information that could be used to help identify areas of the range where exposure is unlikely (*e.g.*, due to elevation restrictions) or very likely (*e.g.*, preferred habitat)?
 - How can the effects on timing be better captured (considering both direct and indirect effects)? For example, for direct effects, at the time of year when a pesticide can be applied, is the species there at that time (*e.g.*, is it only there for part of the year because it is migratory?) or at a life-stage when exposure is or is not likely (*e.g.*, is it at an egg stage, subterranean, or in diapause at that time)? What about the resources it depends on (indirect effects)?
 - Should less refined species ranges (*e.g.*, county-level) be treated differently than those that are more refined [keeping in mind that in many cases a species range is not at a sub-county level for various reasons (*e.g.*, no survey data on private lands, wide-ranging species)]? Is the precision of the analysis equal?
 - Can we incorporate this information to apply a weighting to the overlap analysis (see charge question 5a below)?
- In the pilot BEs, any overlap of the action area with a species range or critical habitat is considered a 'May Affect'.

- **CHARGE QUESTION 5a: Does the overlap approach used in the pilot BEs to determine a 'May Affect/No Effect' determination provide an adequate screening process (one that is protective but not unrealistically conservative)?**
 - When conducting a GIS overlap analysis using datasets with different levels of resolution, what are methods that could be used to ensure that decisions are made based on the datasets' limits of precision (*e.g.*, how can we best avoid 'false positives' and 'false negatives' in the overlap analyses when considering the limits of precision of the datasets used)?
 - Would using a weighting approach for the likelihood of an overlap be useful when making the Step 1 determinations (instead of using only an overlap of the species range/critical habitat and the action area)? For example, for agriculture uses could we incorporate the number of years a cell was classified as the crop in a weighting approach (while still accounting for the duration of the action)?
 - Are there approaches that could be used to screen out species from further analyses besides solely an overlap of the species range/critical habitat and the action area (*e.g.*, if no Step 1 thresholds for plants are exceeded, can plants that are not biologically pollinated be considered 'No Effect', if no other indirect effects are anticipated)?
- **Breakout Group: REFINEMENTS 2 (Refinements to Steps 1 and 2: Non-spatial analysis):**
 - There are a multitude of use patterns on currently registered labels, some which result in potentially higher exposures to non-target organisms than others. For example, although somewhat dependent on chemical fate properties, pesticides applied to large agricultural fields by air are expected to result in higher offsite exposure than pesticides applied to a small area via a ready-to-use spray can.
 - **CHARGE QUESTION 1b: Is there a way to identify use patterns that would result in minimal exposures, such as spot treatments, that may not always need to be fully re-assessed for each pesticide going through the consultation process (*i.e.*, by applying what we have learned from an analysis with another pesticide with a similar use pattern)?**
 - What type of things regarding the pesticide and use site would need to be considered [*e.g.*, the fate properties of the pesticide, the amount of pesticide applied (*e.g.*, per the label and/or based on usage information), the application method used, potential application sites (*e.g.*, ready-to-use spray can)]?
 - Of these fate properties, how could they be considered - keeping in mind use site parameters?
 - Of these use site parameters, how could they be considered (*e.g.*, personal ready-to-use spray can for mosquitos)?

- There are a subset of listed species that are found in places or environments not expected to result in appreciable exposure to most pesticides (those that are not persistent and do not bioaccumulate) (*e.g.*, species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska).
 - **CHARGE QUESTION 2b: Is there a way to identify species that may not always need to be fully re-assessed for each pesticide going through the consultation process (*i.e.*, by applying what we have learned from an analysis with another pesticides)?**
 - Once a species characteristics (*e.g.*, habitat) has been considered, what type of things regarding the fate properties of the pesticide would need to be considered (*e.g.*, aquatic half-life, mobility, bioaccumulation potential, *etc.*)?
 - Of these fate properties, how could they be considered (*e.g.*, a full assessment might not be needed for pesticides that have a $\log K_{ow} < 4$)?
 - What types of biological/ecological attributes of the species would need to be considered (*e.g.*, its habitat)?
 - Of these species characteristics, how can they be considered (this may be different for species and designated critical habitats) (*e.g.*, a full assessment might not be needed for species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska, not present during windows of application; this may not apply to designated)?
- The pilot BE process relies on thresholds for mortality that are based on probabilistic effects endpoints (*e.g.*, 1-in-a-million chance of mortality based on the HC_{05} of a SSD or the lowest LC_{50}/LD_{50} values) compared to deterministic estimated environmental concentrations (EECs) (*e.g.*, 1-in-15 year peak EEC value). Additionally, sublethal thresholds are assessed using deterministic sublethal thresholds (*e.g.*, NOAECs or LOAECs) and deterministic estimated environmental concentrations (EECs) (*e.g.*, 1-in-15 year peak EEC value). The current approach in the BEs is comparing an exposure value to a threshold for possible exceedances [similar to a risk quotient approach (*i.e.*, exposure/effect)].
 - **CHARGE QUESTION 3b: Is there a way to utilize the thresholds that is more informative (for example, in the weight of evidence) and goes beyond a deterministic approach (moving towards a more probabilistic approach for assessing risks as recommended by NAS)?**
 - How could joint probability distributions of effects (the thresholds) and exposures (the EECs) be used to help inform the potential for risk?
 - Are there other probabilistic approaches that can help better inform risk at the individual and field levels?

- When making a “May Affect/No effect’ determination, what are some practicable methods to better determine where both direct and indirect effects are either ‘no effect’ or ‘discountable’ (extremely unlikely to occur)?
 - For example, could an action be “discountable” for certain species (*e.g.*, when there is no direct exposure or effects expected and no or insignificant/discountable effects to prey, pollinators, *etc.*).
- **CHARGE QUESTION 4b: Is there an efficient way to incorporate exposure durations into the analysis of potential effects?**
 - The pilot BEs currently compare all effects thresholds to peak EEC values. How can other durations of potential exposure be utilized and related to available toxicity studies (which are conducted under a range of exposure durations)?
 - Are there factors, other than duration, that should be considered when comparing the effects data to the EECs?

WORKSHOP AGENDA (FINAL)

Joint Interim Approaches to NAS Recommendations for Assessing Risks to Endangered and Threatened Species from Pesticides

WEDNESDAY MORNING, JUNE 29 – Plenary Sessions

TIME	SESSION SCHEDULE
8:00	Registration Opens
9:00	Opening Comments
9:15	Overview of Aquatic Breakout Discussion – Chuck Peck (EPA)
9:55	Overview of Refinements Discussion – Melissa Panger (EPA)
10:20	Break
10:40	Overview of Weight of Evidence Discussion – Kris Garber / Elizabeth Donovan (EPA)
11:20	NatureServe on Range Modeling – Regan Smyth, NatureServe
11:45	Breakout Group Instructions – Bernalyn McGaughey (CSI, Workshop Steering Committee)
12:00	Lunch (on own)

WEDNESDAY AFTERNOON, JUNE 29 – Breakout Sessions

TIME	SESSION SCHEDULE					
GROUPS	AQUATIC 1 (Chuck Peck and George Noguchi)	AQUATIC 2 (Mark Corbin and Al Barefoot)	REFINEMENTS 1 (Bill Eckel/Steve Lennartz and Jake Li)	REFINEMENTS 2 (Melissa Panger and Karen Myers)	WOE 1 (ANIMALS) (Kris Garber and Spencer Mortenson)	WOE 2 (PLANTS) (Elizabeth Donavon and Bernalyn McGaughey)
	Improving Aquatic Modeling: Changes to conceptual and mathematical approaches incorporated into Bins 3 and 4 (flowing waters) <ul style="list-style-type: none"> • Modifications to EPA's current modeling approach and parameterization to flowing bins • Use of other watershed models (e.g., SWAT, WARP) 	Improving Aquatic Modeling: Evaluating watershed model results <ul style="list-style-type: none"> • Use of multiple lines-of-evidence to evaluate watershed model results • Role of and metadata requirements for use of monitoring data in evaluating watershed results 	Refinements to Steps 1 and 2: Spatial analysis <ul style="list-style-type: none"> • Methods to better identify pesticide use sites (ag and non-ag) • Methods to better understand the distribution of individuals within a listed species range • Improvements to the overlap analyses between species range and potential pesticide use 	Refinements to Steps 1 and 2: Non-spatial analysis <ul style="list-style-type: none"> • Identification of use patterns (e.g., those resulting in minimal exposures) and/or listed species (e.g., those found on uninhabited islands) that may not need to be fully evaluated • Methods to utilize thresholds that are more probabilistic • Methods to incorporate exposure durations into the analysis of potential effects 	Weight of Evidence for Listed <u>Animals</u> <ul style="list-style-type: none"> • Improvements to the evaluation of information and criteria used to draw risk conclusions • Incorporation of additional information into the weight of evidence approach 	Weight of Evidence for Listed <u>Plants</u> <ul style="list-style-type: none"> • Improvements to the evaluation of information and criteria used to draw risk conclusions • Incorporation of additional information into the weight of evidence approach

ROOMS	Leopold (10-12) (12 registered)	Beatie (17-20) (16 registered)	Roosevelt (24) (19 registered)	Stickel (30+) (21 registered)	Hamilton A (16) (16 registered)	Hamilton B (16) (13 registered)
1:00	Aquatic 1 – Charge Questions Set 1	Aquatic 2 – Charge Questions Set 1	Refinements 1 – Charge Questions Set 1	Refinements 2 – Charge Questions Set 1	WOE 1 (Animals) – Charge Questions Set 1	WOE 1 (Plants) – Charge Questions Set 1
3:00	BREAK					
3:30	Aquatic 1 – Charge Questions Set 1	Aquatic 2 – Charge Questions Set 1	Refinements 1 – Charge Questions Set 1	Refinements 2 – Charge Questions Set 1	WOE 1 (Animals) – Charge Questions Set 1	WOE 1 (Plants) – Charge Questions Set 1
5:30	ADJOURN					
5:45	NO-HOST SOCIAL - Buffalo Wild Wings (Next Door to Meeting Area)					

THURSDAY, JUNE 30 – Breakout Sessions

TIME	SESSION SCHEDULE					
8:30	Registration Opens					
GROUPS	AQUATIC 1	AQUATIC 2	REFINEMENTS 1	REFINEMENTS 2	WOE 1 (ANIMALS)	WOE 2 (PLANTS)
9:00	Aquatic 1 – Charge Questions Set 2	Aquatic 2 – Charge Questions Set 2	Refinements 1 – Charge Questions Set 2	Refinements 2 – Charge Questions Set 2	WOE 1 (Animals) – Charge Questions Set 2	WOE 1 (Plants) – Charge Questions Set 2
10:30	BREAK					
11:00	Aquatic 1 – Charge Questions Set 2	Aquatic 2 – Charge Questions Set 2	Refinements 1 – Charge Questions Set 2	Refinements 2 – Charge Questions Set 2	WOE 1 (Animals) – Charge Questions Set 2	WOE 1 (Plants) – Charge Questions Set 2
12:30	LUNCH (on own)					
1:30	Aquatic 1 – Finalize Responses	Aquatic 2 – Finalize Responses	Refinements 1 – Finalize Responses	Refinements 2 – Finalize Responses	WOE 1 (Animals) – Finalize Responses	WOE 1 (Plants) – Finalize Responses
2:30	BREAK					
2:45	Final Overview – Breakout Groups Report Out (30 min each)					
5:45	Wrap-up					
6:00	Adjourn					

The behaviour of 39 pesticides in surface waters as a function of scale

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Abstract:

A portion of applied pesticides runs off agricultural fields and is transported through surface waters. In this study, the behaviour of 39 pesticides is examined as a function of scale across 14 orders of magnitude from the field to the ocean. Data on pesticide loads in streams from two US Geological Survey programs were combined with literature data from field and watershed studies. The annual load as percent of use (LAPU) was quantified for each of the fields and watersheds and was used as the normalization factor across watersheds and compounds. The in-stream losses of each pesticide were estimated for a model stream with a 15 day travel time (similar in characteristics to the upper Mississippi River). These estimated in-stream losses agreed well with the observed changes in apparent LAPU values as a function of watershed area. In general, herbicides applied to the soil surface had the greatest LAPU values and minimal in-stream losses. Soil-incorporated herbicides had smaller LAPU values and substantial in-stream losses. Insecticides generally had LAPU values similar to the incorporated herbicides, but had more variation in their in-stream losses. On the basis of the LAPU values of the 39 pesticides as a function of watershed area, a generalized conceptual model of the movement of pesticides from the field to the ocean is suggested. The importance of considering both field runoff and in-stream losses is discussed in relation to interpreting monitoring data and making regulatory decisions.

KEY WORDS pesticides; insecticides; herbicides; runoff; stream; load; modelling; surface water

INTRODUCTION

The movement of pesticides from agricultural fields and through the surface water network has been studied extensively. Although each pesticide behaves differently, the processes that govern their behaviour and fate have been identified and, to some extent, quantified. Atrazine was used as an example of a pesticide that exhibits ideal behaviour in its movement from agricultural fields to the ocean (Capel and Larson, 2000). From a field runoff perspective, atrazine is ideal because it is widely used, typically applied on the bare soil surface, and is observed in most runoff events. From a surface water perspective, it is one of the most commonly observed herbicides in streams and rivers, and has relatively slow loss processes from the water column. By using the parameter of annual load (in field runoff or in the stream) normalized to annual use (load as percent of use, LAPU), the behaviour of atrazine in 414 watersheds across the range of scales was easily compared. It was observed that the LAPU value of atrazine did not vary substantially with scale in watersheds that ranged through 14 orders of magnitude in area. The variability that did exist in the LAPU values was attributed to year-to-year differences in weather within a given watershed and differences in the terrestrial characteristics among the various watersheds. When the logarithm of annual atrazine load was regressed against the logarithm of annual atrazine use, the slope was very close to unity (1.04 ± 0.02), suggesting that the average runoff behaviour is consistent across a wide range of watershed areas and characteristics. The central tendency of the atrazine LAPU value was defined as the median small-scale LAPU (small scale means agricultural fields and watersheds <100 000 ha). (Only the small watersheds

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were used to minimize the effect of any in-stream loss of atrazine. Although the losses will be minimal for atrazine, when this method is applied to other pesticides discussed in this paper the losses could be substantial.) The atrazine median small-scale LAPU was 0.66%. On the basis of these observations, Capel and Larson (2000) concluded that the extent of atrazine runoff was determined by the characteristics of atrazine itself (physical/chemical properties, formulation, and application method), as well as terrestrial or climatic factors. This paper will examine 39 pesticides in a similar fashion to determine whether a similar phenomenon is observed.

Many different organic compounds are used to control pests in agricultural crops. Wauchope (1978, p. 450), in his review of the literature on pesticide runoff from agricultural fields, wrote, 'pesticides are different. The only property that these chemicals have in common is their broad function as tools for crop protection. Once they leave the spray nozzle they show vastly different persistences, mobilities, and toxicities'. Each individual organic pesticide has its particular set of physical/chemical properties (solubility, vapour pressure, Henry's law constant, etc.). Each pesticide is generally marketed in only one or a few different formulations (granular, wettable powder, emulsifiable concentrate, etc.) and applied in the field by one or more different methods (surface, soil incorporated, foliar, etc.). These three attributes of a particular pesticide are often interrelated. As an example, butylate, a herbicide used on corn, has a relatively high vapour pressure (Table I) and, consequently, is almost always incorporated into the soil (applied at depth) so that its efficacy will not be lost due to volatilization to the atmosphere.'

Concentrations of 39 current-use pesticides (Table I) have been measured in rivers across the United States in two US Geological Survey (USGS) Programs [National Stream-Quality Accounting Network (NASQAN) and National Water-Quality Assessment Program (NAWQA)]. These data have been used to calculate annual LAPU values. The LAPU values from the USGS programs were combined with LAPU values for studies of the 39 pesticides in runoff and in streams, which are reported in the scientific literature. The LAPUs for individual pesticides from field-scale and watershed-scale studies are examined to help understand the controls on the extent of field runoff and in-stream losses. By comparing the LAPUs for the different chemicals, the relative importance of chemical properties, formulations, and application practices are discussed. On the basis of these observations, a generalized conceptual model of the movement of pesticides from the field to the ocean is suggested.

Factors controlling field runoff

The extent to which a pesticide runs off an agricultural field is determined by the unique combination of climatic, terrestrial, chemical, and management factors that characterize each field, crop, and year combination. Each of these factors has been studied in detail, and numerous reviews on this subject have been published (Wauchope, 1978; Weber *et al.*, 1980; Wauchope and Leonard, 1980; Leonard, 1988, 1990; Willis and McDowell, 1982).

The most important factor controlling the extent of runoff is rainfall, especially the timing and intensity of the first substantial rain after application. The greatest amounts of pesticides are lost from the field when the first runoff-producing rain occurs soon after application. Subsequent runoff-producing rains tend to cause lesser amounts of pesticides to leave the field. Many field runoff studies have used simulated rain to control the timing and amount of the precipitation (Capel *et al.*, 2001). Frequently, investigators exceed normal rainfall amounts in these studies to simulate worse-case conditions. Wauchope (1978) refers to these as catastrophic rain events, and LAPUs >2% are often observed.

Terrestrial factors also influence the extent of pesticide runoff. Important factors that have been identified include soil-particle size and organic-matter content, and topographic slope. Particle size can influence the rate of infiltration of water; generally, smaller particle sizes yield lower infiltration rates and more runoff. Particle size and soil organic-matter content influences runoff by affecting the extent of sorption of the pesticide. Chemicals strongly sorbed to soil particles tend to leave the field associated with particles, whereas chemicals weakly sorbed tend to leave the field in the aqueous phase. Efforts to control soil

Table I. Agricultural pesticide use, properties, and estimated in-stream loss

Pesticide (use ^a)	Major application method ^b	National use rank ^c	Soil half-life (days) ^d	Aqueous half-life group ^e	log K_H ^f	log K_{oc} ^g	Major loss process ^h	Estimated % lost in 15 days ⁱ
Alachlor (H)	sur	7	27	E	-7.67	2.23	T	14
Atrazine (H)	sur	1	173	G	-8.55	2.00	T	2
Azinphos-methyl (I)	fol	48	10	C	-8.51	2.61	T	77
Benfluralin (H)	inc	105	80	C	-3.54	3.95	T,V	95
Butylate (H)	inc	19	28	E	-4.09	2.60	V	74
Carbaryl (I)	fol	32	14	C	-9.36	2.36	T	77
Carbofuran (I)	inc	24	41	C	-9.31	2.02	T	77
Chlorpyrifos (I)	inc	12	43	C	-4.97	3.78	T	86
Cyanazine (H)	sur	3	13	E	-11.53	2.30	T	14
DCPA (H)	sur	76	50	F	-5.57	1.18	T	45
Diazinon (I)	fol	62	7	E	-6.40	2.76	T	16
Disulfoton (I)	fol	60	37	D	-5.67	3.25	T	45
EPTC (H)	inc	13	18	C	-5.00	2.30	T	85
Ethalfuralin (H)	inc	47	41	B	-3.90	3.71	T	100
Ethoprop (I)	inc	67	29	E	-6.85	2.15	T	14
Fonofos (I)	fol	45	37	D	-5.17	2.94	T,V	54
Lindane (I)	sur	161	423	G	-5.84	3.00	V	10
Linuron (H)	sur	54	82	D	-6.13	2.91	T	40
Malathion (I)	fol	40	9	B	-7.65	3.26	T	99
Methyl parathion (I)	fol	16	10	D	-6.69	3.70	T	42
Metolachlor (H)	sur	2	141	E	-7.64	2.26	T	14
Metribuzin (H)	sur	46	47	F	-10.46	1.71	T	36
Molinate (H)	pat	25	13	C	-5.85	1.92	T	79
Napropamide (H)	inc	99	48	C	-9.09	2.66	T	77
Parathion (I)	fol	55	14	D	-6.63	3.88	T	44
Pebulate (H)	inc	90	8	D	-4.59	2.62	T,V	70
Pendimethalin (H)	sur	9	174	F	-4.92	4.13	T,V	67
Permethrin (I)	fol	—	42	D	-5.73	4.59	T,S	66
Phorate (I)	sur	34	37	F	-5.01	2.82	T,V	58
Pronamide (H)	sur	127	45	F	-5.74	2.90	T	43
Propachlor (H)	sur	31	9	D	-6.97	1.90	T	37
Propanil (H)	sur	20	1	A	-7.27	2.17	T	100
Propargite (I)	fol	39	84	F	-7.47	4.61	S,T	65
Simazine (H)	sur	26	89	D	-8.47	2.11	T	36
Terbacil (H)	sur	93	212	G	-9.83	1.74	T	2
Terbufos (I)	inc	21	12	B	-4.62	2.70	T	99
Thiobencarb (H)	pat	64	19	C	-3.54	2.95	T,V	95
Triallate (H)	inc	53	74	E	-4.95	3.38	V	47
Trifluralin (H)	inc	10	81	E	-4.01	4.14	V	79

^a H: herbicide, I: insecticide.^b Sur: soil surface applied; inc: incorporated into soil; fol: foliar applied; pat: added to rice paddy (Wauchope *et al.*, 1992).^c Agricultural use rank by mass applied (Gianessi and Anderson, 1996).^d USDA, (1999).^e A: ~0.5–1 day; B: ~1–4 days; C: ~4–12 days; D: ~12–40 days; E: ~40–120 days; F: ~120–420 days; G: ~420–1200 days; Mackay *et al.* (1997).^f log Henry's law constant (K_H , 20 °C, atm m³ mol⁻¹; USDA, 1999).^g log organic-carbon normalized water–solid distribution coefficient (K_{oc} , l kg⁻¹; USDA, 1999).^h S: sorption/sedimentation; T: transformation; V: volatilization. Two major processes are identified, if they differ by less than a factor of two.ⁱ Estimated losses are for the conditions: POC = 1 mg l⁻¹; mean depth, 2 m; mean water velocity, 1 m s⁻¹; temperature, 20 °C; wind speed, 1 m s⁻¹.

erosion could significantly reduce the runoff of strongly sorbed pesticides, but would have little effect on others.

The chemical structure of a pesticide determines its properties. These include water solubility, acid dissociation constant, ionic charge, vapour pressure, and resistance to physically, chemically, and biologically induced transformation reactions. For nonionic compounds, the water solubility is inversely related to the extent of sorption to soil particles. Pesticides with relatively high vapour pressures are easily lost from the soil via volatilization if they are not incorporated into the soil during application. Loss to the atmosphere influences the extent of runoff by diminishing the amount of the pesticide available in the soil. The same holds true for the kinetics of the transformation reactions. The faster any type of reaction transforms the pesticide in the field, the less is available over the season to be lost in runoff.

Wauchope (1978) showed that one way of organizing the runoff behaviour of various pesticides is by their formulations. Pesticides formulated as wettable powders (generally herbicides applied to the soil surface) had the greatest tendency toward runoff of the pesticides still used in agriculture. (The organochlorine insecticides had the greatest tendency to runoff, but most of them are no longer in use.) Wauchope (1978) suggested that a LAPU of about 2% would be a good estimate for compounds formulated as wettable powders for fields with low slopes. Wauchope (1978) also suggested that pesticides formulated as an emulsion had LAPUs of 1% or less. Many of the low solubility compounds and foliar-applied insecticides are in this group. The pesticides that generally had the lowest LAPUs (<0.5%) included the soil-incorporated compounds and the highly water-soluble pesticides that were formulated as aqueous solutions. If only organic pesticides are considered, paraquat was the only consistent exception to these general observations. Although paraquat is highly water soluble, it is cationic and, therefore, strongly associates with soil particles.

Many types of agricultural practice come into play when determining the extent of runoff of pesticides, as well as water and soil, including choice of crop, chemical application method, chemical formulation, tillage method, and best management practices (BMPs). The choices made are based on a consideration of practical, economic, and environmental concerns. The choice of crop and chemical is dependent on climate and soil. The choice of chemical, application method, and tillage method is dependent on the equipment available to the farmer and the application method recommended by the chemical manufacturer. The choice of BMP, such as buffer strips, contour ploughing, or reduced tillage, generally is based on local environmental concerns. Many BMPs are designed to decrease the amount of soil that is lost to surface waters, but a few are designed to reduce water runoff. The different BMPs affect the runoff of the more water-soluble pesticides to various extents.

After a pesticide runs off the field and enters a stream, its behaviour and fate will be governed by the properties of the chemical (particularly water solubility, Henry's law constant, and persistence) and the properties of the stream (particularly travel time, depth, solids concentration, and the physical, chemical, and/or microbiological constituents that cause transformation). Although the behaviour of each chemical in each river will be unique, there are ranges of chemical and environmental properties that bracket most situations. By examining these ranges, the relative importance of the three general loss processes (transformation, volatilization, and sorption/sedimentation) can be evaluated for individual pesticides in a variety of riverine environments. These model equations, given below, are illustrated with a simple example. The model equations then will be applied to the 39 pesticides included in this study to help understand the field observations.

METHODS

Sampling and analysis

Samples were obtained from the largest rivers (Colorado, Columbia, Mississippi, and Rio Grande Rivers and their major tributaries) in the USA from October 1996 through September 1998 as part of the NASQAN program. For a given pesticide, only those watersheds that met minimum use criteria (1 kg km^{-2}) are included

in this analysis. The number of NASQAN watersheds varies from 0 to 14, depending on the compound. A more detailed description of the watersheds, details of the sampling schedule and the sampling techniques, are described by Hooper *et al.* (2001) and Kelly and Hooper (2001).

Samples were also obtained from 43 streams and rivers from October 1992 through September 1994 as part of the NAWQA program. For a given pesticide, only those watersheds that met minimum use criteria (1 kg km^{-2}) are included in this analysis. The number of NAWQA watersheds varies from 0 to 34, depending on the compound. The smaller watersheds generally were intensively cropped and indicative of the agriculture of the region. A more detailed description of the watersheds, the details of the sampling schedule and the sampling techniques are described by Larson *et al.* (1999) and Shelton (1994).

The NASQAN and NAWQA programs used the same analytical procedure for the pesticides. Briefly, a 1 l water sample was processed through a combusted 142 mm glass-fibre filter (nominal $0.7 \mu\text{m}$ pore openings). The filtered water was spiked with surrogates. After the pesticides were isolated from the water with a 500 mg octadecyl solid-phase extraction column, the column was dried and the pesticides eluted with solvent. The solvent volume was reduced with a gentle stream of nitrogen. The extract then was analysed by gas chromatography/mass spectrometry using selective ion monitoring. The method detection limits ranged from 1 to 10 ng l^{-1} . Details of the analytical procedure, including quality assurance results, are in Zaugg *et al.* (1995).

Literature data of LAPU values from studies for fields and streams

The international scientific literature was searched for studies that quantified the selected pesticides in field runoff or streams by means of two computerized bibliographic databases: Chemical Abstracts and AGRICOLA. Only articles that contained enough information to calculate a LAPU value were retained. The areas of the controlled field studies ranged from $0.000\,023$ to 60 ha . The areas of the watershed studies ranged from 58 to $315\,620\,000 \text{ ha}$. Throughout this paper, both of these groups are referred to as watersheds.

All controlled plot and field studies that were conducted outside of the laboratory and lasted for more than 1 day were included in this analysis without screening. The duration of most field studies was weeks to months. A few, with a shorter duration, employed simulated rain. Because the majority of pesticide runoff almost always occurs in the first major runoff event following application, the results of the short duration studies are similar to the results of the studies of longer duration. The *a priori* decision to include all studies with duration greater than 1 day was made to limit any bias introduced by deleting certain field studies. The exception to this is the single field-scale study that examined EPTC (Spencer and Cliath, 1991). This study examined the loss of EPTC after it was put into irrigation water for alfalfa. Because most EPTC is used on corn and applied as incorporated herbicide, the losses in the irrigation water study would not be representative of the major use of this compound and, therefore, were not included in Table II.

Load calculations and pesticide use estimates

The annual loads of the pesticides in streams from both the NASQAN and NAWQA programs were calculated as described in Larson *et al.* (1995) by summing up estimated daily loads. The daily loads were calculated by multiplying the daily stream discharge by the daily concentration. Daily discharge values were available, but pesticide concentrations were measured less frequently. Pesticide concentrations for days that were not sampled were estimated by linear interpolation from the concentrations measured on the closest preceding and following days in which pesticides were quantified. If the pesticide was not detected, a value of zero was used for the concentration. The loads of the pesticides from studies published in the literature were used as reported. In some cases, loads that were reported as '<' were removed from the statistical analysis described below when the data were transformed by the base-10 logarithm.

For the data from the NASQAN and NAWQA programs, pesticide use was based on county-level use estimates (Gianessi and Anderson, 1996). The estimated use of each pesticide in each county in the watershed was summed to yield a total use value. For counties only partially in the watershed, the pesticide's use was

Table II. Summary of field-based and watershed-based LAPU values of the 39 pesticides. The median small-scale LAPU is based on observations from both field and small watersheds (<100 000 ha)

Compound	Field-based observations (≤ 60 ha)			Median small-scale LAPU (%)	Stream-based observations (≥ 100 ha)								
	N		Mean \pm SD		Watersheds $< 100\,000$ ha			Watersheds $> 100\,000\,000$ ha					
	N	% $<^a$			Median	Mean \pm SD	N	Median	Mean \pm SD	N			
Alachlor	113	6	0.36	2.1 \pm 0.3	0.27	146	5	0.12	0.38 \pm 0.83	34	0.13	0.17 \pm 0.15	34
Atrazine	181	6	0.76	1.7 \pm 0.9	0.66	226	3	0.47	1.7 \pm 3.0	95	1.5	1.9 \pm 1.5	51
Cyanazine	69	7	0.10	3.7 \pm 0.4	0.68	135	5	0.13	1.1 \pm 2.5	28	0.82	1.2 \pm 1.1	43
DCPA	3	0	1.4	1.3 \pm 0.096	1.2	5	0	1.2	1.2 \pm 1.1	3	—	—	0
Linuron	16	6	0.040	0.45 \pm 0.88	0.038	19	58	0.024	0.090 \pm 0.15	10	<	<	6
Metolachlor	102	3	0.60	1.2 \pm 0.9	0.50	175	3	0.25	1.0 \pm 1.6	54	0.80	1.0 \pm 0.82	51
Metribuzin	92	1	0.71	1.8 \pm 0.5	0.70	61	8	0.053	0.40 \pm 0.73	5	0.28	0.25 \pm 0.14	6
Pendimethalin	6	17	0.046	0.035 \pm 0.024	0.0050	71	44	0.0043	0.013 \pm 0.018	30	<	0.0066 \pm 0.0092	24
Pronamide	0	—	—	—	— ^b	1	0	0.020	0.020	1	—	—	0
Propachlor	11	0	0.25	1.4 \pm 0.9	0.22	15	27	0.051	0.065 \pm 0.053	4	0.0073	0.040 \pm 0.068	9
Propanil	0	—	—	—	— ^b	1	0	6.4	—	0	—	—	0
Simazine	26	23	0.16	0.82 \pm 0.4	0.52	40	3	1.6	2.6 \pm 2.9	12	5.2	6.5 \pm 4.7	14
Terbacil	0	—	—	—	— ^b	1	0	0.73	0.73	1	—	—	0
Benfluralin	0	—	—	—	<	4	100	<	<	4	—	—	0
Butylate	0	—	—	—	0.0039	38	44	0.0039	0.082 \pm 0.21	13	<	0.019 \pm 0.059	15
EPTC ¹	0	—	—	—	0.034	82	12	0.034	0.16 \pm 0.47	21	0.0080	0.021 \pm 0.037	37
Ethalfuralin	0	—	—	—	<	12	67	<	0.13 \pm 0.42	10	—	—	0
Napropamide	0	—	—	—	1.6	3	0	1.6	1.6 \pm 0.85	2	—	—	0
Pebulate	0	—	—	—	0.00027	5	40	0.0003	1.0 \pm 1.7	3	—	—	0
Triallate	0	—	—	—	0.0023	10	20	0.0022	0.012 \pm 0.020	4	<	<	0
Trifluralin	36	11	0.18	0.23 \pm 0.25	0.054	69	26	0.012	0.06 \pm 0.15	25	0.0043	0.0064 \pm 0.0087	24
Molinate	0	—	—	—	4.9	3	0	4.9	4.9 \pm 6.7	2	—	—	0

^aPercent less of watersheds in which a LAPU value could not be calculated due to water concentrations that were below the detection limit.

prorated on the basis of percentage of land used in row crop agriculture in the watershed (Gilliom and Thelin, 1997). For the studies from the literature, the masses of the pesticides applied were used in this analysis as originally reported.

Factors and model equations of in-stream losses of pesticides

Pesticides can undergo physically, chemically, and (or) biologically induced transformation reactions. Depending on the conditions of the environments, different types of transformation process can act simultaneously on a pesticide, but generally one reaction is the most important. The rate of transformation is often described by pseudo first-order kinetics with a rate constant k_t that is the sum of all physically, chemically, and (or) biologically induced reactions. The percent loss as a function of time t can be calculated by

$$(\ln C/C_0) \times 100 = -k_t t \quad (1)$$

where C_0 is the initial total concentration and C is the total concentration at time t . Figure 1(a) shows the percent loss of a pesticide as a function of surface water half-life for a range of travel times that bracket most riverine systems. As an example, for a 15 day travel time, typical of the Mississippi River from Iowa to the Gulf of Mexico (Pereira and Rostad, 1990), only those pesticides that have aquatic half-lives less than about 47 days will have losses $\geq 20\%$.

The rate loss of a pesticide from the water column via volatilization is a function of chemical properties (Henry's law constant and diffusivities in air and water), riverine properties (depth, water temperature and turbulence), and atmospheric properties (air temperature and wind speed). Volatilization is often modelled after the two-film theory, which suggests that the mass flux of the contaminant is the product of the overall mass transfer coefficient ν_{OL} and the difference between the concentrations of the pesticide in the water and air. Often expressed as the resistance to air–water transfer, $1/\nu_{OL}$ is the sum of the resistance of transfer through the two stagnant films (water and air)

$$1/\nu_{OL} = 1/\nu_W + 1/\nu_A \quad (2)$$

where ν_W and ν_A are the mass transfer coefficients in the stagnant water and air films respectively. Schwarzenbach *et al.* (1993), in their review of the literature, suggest that ν_W and ν_A can be estimated by the relationships

$$\nu_W \approx (D_{w,i}/D_{w,O_2})^{0.57} (4 \times 10^{-5} (u_{10})^2 + 4 \times 10^{-4}) \quad (3)$$

and

$$\nu_A \approx (D_{a,i}/D_{a,H_2O})^{0.67} (0.2u_{10} + 0.3)(K_H/RT) \quad (4)$$

where $D_{w,i}$ ($\text{cm}^2 \text{s}^{-1}$), is the diffusivity of compound i in water, D_{w,O_2} ($\text{cm}^2 \text{s}^{-1}$) is the diffusivity of oxygen in water, $D_{a,i}$ ($\text{cm}^2 \text{s}^{-1}$) is the diffusivity of compound i in air, D_{a,H_2O} ($\text{cm}^2 \text{s}^{-1}$) is the diffusivity of water in air, u_{10} (m s^{-1}) is the wind speed at 10 m above the river surface, R ($0.082 \text{ l atm mol}^{-1} \text{ K}^{-1}$) is the gas constant, T (K) is the temperature, and K_H (l atm mol^{-1}) is Henry's law constant.

Because only the dissolved fraction of the pesticide is available for volatilization, the rate of loss of a pesticide to the atmosphere via volatilization R_v , assuming its air concentration is zero, is

$$R_v = -k_v C(1 - f_p) = -(\nu_{OL}/z)C(1 - f_p) \quad (5)$$

where k_v is the pseudo first-order rate constant, f_p is the fraction of the pesticide associated with the particulate phase, and z (m) is the mean depth of the river. For a given wind speed, this equation can be rearranged and solved for a specific degree of loss of the pesticide. Assuming a wind speed of 1 m s^{-1} , Figure 1(b) shows the ranges of K_H values and riverine depths that would result in a 20% loss of a pesticide for a range of riverine travel times. Using the example of the Mississippi River described above ($z = 2 \text{ m}$), only those pesticides with a K_H value $\geq 1 \times 10^{-3}$ would have a loss of 20% in a 15 day travel time.

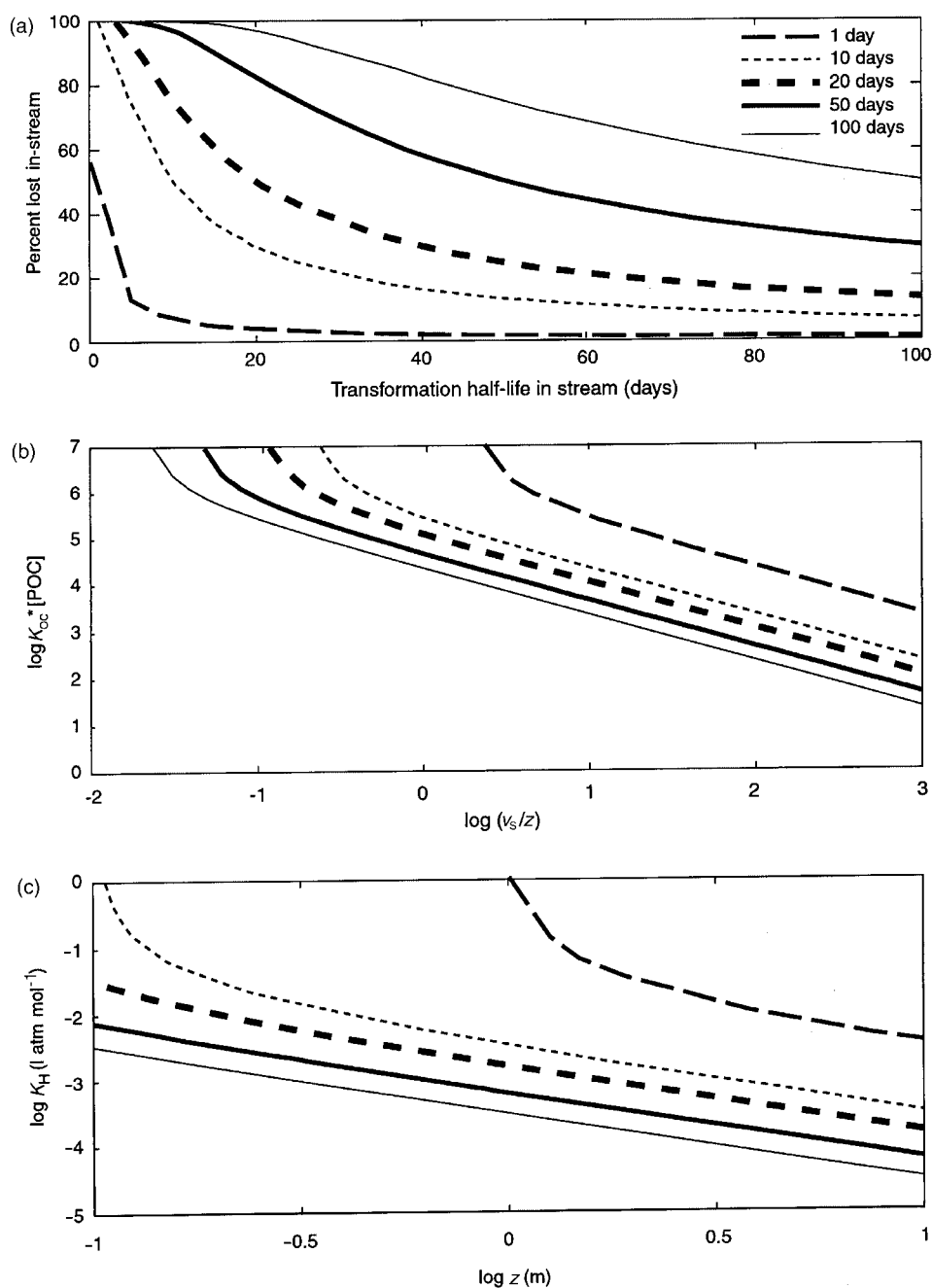


Figure 1. (a) Percent in-stream loss of a pesticide as a function of surface water half-life for a range of travel times that bracket most riverine systems. (b) Typical ranges of Henry's law constant K_H and mean stream depth that would result in a 20% loss of a pesticide for a range of travel times. (Average wind speed assumed to be 1 m s^{-1} .) (c) Typical ranges of the product of organic-carbon based sorption coefficient K_{oc} and particulate organic carbon concentration (POC) and the product of mean stream depth and particle settling velocity that would result in a 20% loss of a pesticide for a range of travel times. In all three graphs, the lines represent a 20% loss for a river similar to the upper Mississippi River and a 15 day travel time

The rate loss of a pesticide from the water column via sorption/sedimentation is conceptually a two-step process. The first step, sorption, is largely governed by the chemical. The physics of the river and the types of aquatic particle largely govern the second step, sedimentation. The driving force for sorption of nonionic pesticides is their hydrophobicity, which is quantified through water solubility. Several investigators (see review in Schwarzenbach *et al.* (1993)) have shown that the extent of sorption for a given chemical is a function of its water solubility and the fraction of the aquatic particle that consists of organic carbon f_{oc} . Wanner *et al.* (1989) have used these relations to calculate the fraction of the chemical in the particulate phase f_p

$$f_p = (K_{oc}[POC]) / (1 + K_{oc}[POC]) \quad (6)$$

where K_{oc} ($l\ kg^{-1}$ organic carbon), is the organic-carbon normalized distribution coefficient and $[POC]$ ($kg\ l^{-1}$) is the concentration of particulate organic carbon. This can be rearranged to isolate the effect of the chemical (K_{oc}) and riverine (POC) properties on the fraction in the particulate phase

$$K_{oc}[POC] = (f_p \times 10^{-6}) / (1 - f_p) \quad (7)$$

The factor of 10^{-6} is for unit conversion from $l\ kg^{-1}$ for POC in Equation (6), to the units of $mg\ l^{-1}$, the units in which POC is normally reported.

Once the pesticide is sorbed to the particle, it can be removed from the water column through sedimentation. Wanner *et al.* (1989) have suggested that the removal R_s can be described as

$$R_s = -k_s f_p C = -(v_s/z) f_p C \quad (8)$$

where k_s is the pseudo first-order rate constant for sedimentation, v_s is the mean settling velocity, and z is the mean depth of the river. Figure 1(c) shows the range of values of chemical and riverine properties that would result in a 20% loss of a pesticide for a range of riverine travel times. In Figure 1(c), the y-axis brackets the product of the normal ranges of K_{oc} (1 to 10 000 $l\ kg^{-1}$) and $[POC]$ (1 to 100 $mg\ l^{-1}$) and the x-axis brackets the product of the normal ranges of v_s (0.01 to 10 $m\ day^{-1}$) and z (0.1 to 10 m). As in the example above ($v_s = 2\ m\ day^{-1}$, $z = 2\ m$, $[POC] = 1\ mg\ l^{-1}$), only those chemicals with $K_{oc} > 6 \times 10^4$ would have losses of $\geq 20\%$ in a 15 day travel time.

RESULTS

Plot- and field-scale observations of LAPU

The statistical summary of the LAPUs for the 39 individual compound is presented in Table II. The scales of these plot and field studies ranged from 0.23 m^2 to 60 ha (about six orders of magnitude). For 17 of the 39 compounds, no literature studies were found that reported a LAPU or the data needed to calculate a LAPU. For another eight compounds, fewer than ten LAPUs are reported in the literature. In this group, many of the values reported for a compound were from a single study.

The relationship between the mean and median LAPU values differs among individual compounds. The mean was greater than the median for 16 of the 22 compounds, although the difference between the mean and median LAPU values was less than a factor of two for 14 of the 22 compounds. The largest difference between the mean and median was for cyanazine, which had a very high mean LAPU value because one study used simulated rain and reported ten observations with a LAPU $> 10\%$ (Baker *et al.*, 1978). There were ten compounds with a mean LAPU $> 1\%$, a median LAPU $\geq 0.6\%$, or both. This group included seven surface-applied herbicides (alachlor, atrazine, cyanazine, DCPA, metolachlor, metribuzin, and propachlor) and three insecticides (carbofuran, fonofos, and terbufos). Because DCPA has only three observations, it is uncertain whether DCPA belongs in this group of pesticides with high LAPU values.

The surface-applied corn and (or) soybean herbicides (alachlor, atrazine, cyanazine, metolachlor, and metribuzin) were by far the most commonly studied compounds at the plot and field scale (Table II). This group of five compounds accounts for 72% of all of the LAPU values reported for the 39 compounds. Five insecticides had at least ten reported LAPU values, but a LAPU value was reported for only one soil-incorporated herbicide (trifluralin). It should be noted that the three groups have substantially different numbers of observations of LAPU. There were 619, 36, and 119 observations of LAPU for the surface-applied herbicides, soil-incorporated herbicides and insecticides respectively.

All three groups also had some observations of LAPUs that were reported as zero or less than the minimum quantifiable value (Table II). These zero and less-than values represent 5%, 11%, and 10% of the LAPU values for the surface-applied herbicides, soil-incorporated herbicides, and insecticides respectively. The largest observed LAPU values (those >90th percentile) ranged from 5.4 to 23%, 0.47 to 1.1% and 1.9 to 11% for the surface-applied herbicides, soil-incorporated herbicides and insecticides respectively. A *t*-test done on the LAPU data after transformation using the cubic root obtained a nearly normal distribution. The mean of the LAPUs for the surface-applied group was significantly different from the means of the soil-incorporated and insecticide groups ($p < 0.001$ for both).

In his review of pesticides in runoff, Wauchope (1978) made some generalizations based on pesticide formulation and application method. Although some of the studies included in this analysis were also used in Wauchope's work, a considerable amount of additional research was conducted on the runoff characteristics of these chemicals. He suggested that the LAPUs of surface-applied herbicides (triazines and other wettable powders), soil-incorporated herbicides, and insecticides would be about 2%, 0.5%, and 0.5% respectively. This generalization, made over 20 years ago, is in good agreement with the mean LAPU values of the three groups (1.8%, 0.23%, and 0.84% for the surface-applied herbicides, soil-incorporated herbicides and insecticides respectively).

Estimated in-stream losses of specific pesticides

As pesticides run off the field and into the surface water system, they enter an environment that is water dominated rather than particle dominated. The extent of in-stream losses of individual pesticides will vary because of the characteristics of the streams through which they are transported, as well as the characteristics of the chemical itself. The surface water system spans a continuum of streams from agricultural ditches draining a few farm fields up to the large regional rivers that drain into the ocean. Given this diversity, the characteristics of the streams (physical, chemical, and biological) will vary tremendously. It is not possible, in the context of this paper, to model specifically how individual riverine environments will process individual pesticides. Therefore, a 'standard' stream is defined to compare the relative losses of the different pesticides. This stream is defined by the input parameters described above: mean depth, 2 m; mean water velocity, 2 m day⁻¹; mean wind speed, 1 m s⁻¹; temperature (air and water), 20°C; POC, 1 mg/l⁻¹; neutral pH; a 'typical' microbiological community; and 'typical' spring sunlight conditions. This 'standard' stream is representative of the upper Mississippi River in early June, when the largest load of pesticides is transported.

Because each of the in-stream loss processes is acting on the pesticide simultaneously, the rate constants must be summed to yield an overall rate of loss. On the basis of Equations (1), (5), and (8), the one or two most important loss processes for each chemical for these stream conditions are presented in Table I.

The pesticides in this study were chosen with the criterion that they exist predominately in the dissolved phase in aqueous environments, because only the filtered water was analysed. Because of this, only two pesticides, propargite and permethrin, have sorption/sedimentation as one of their important loss processes. There are some hydrophobic pesticides (i.e. DDT, chlordane) not targeted in this study that would readily be lost from the water column through sorption/sedimentation.

Volatilization is one of their dominant loss processes for ten of the 39 pesticides. Five of these pesticides (benfluralin, pebulate, pendimethalin, triallate, and trifluralin) are herbicides that are generally incorporated in the soil during application because of their volatility. It is interesting to note that other soil-incorporated

herbicides (EPTC, ethalfuralin, and napropamide) were calculated to be lost faster through transformation reactions than through volatilization. Three of the insecticides (fonofos, lindane, and phorate) were calculated to be lost predominately through volatilization. Finally, thiobencarb, a herbicide normally applied to standing water in rice paddies, can be lost through volatilization as well as transformation.

In-stream transformation (chemically and (or) biologically induced reactions) was the predominate loss mechanism for the remainder of the pesticides. The in-stream transformation rates are based on a review of literature data by Mackay *et al.* (1997). The pesticides were classified into seven transformation groups (Table I). The centre of the half-life range for each group was used in these calculations. Although transformation reactions were an important loss mechanism for all of these compounds, the calculated rate of transformation varied greatly among the pesticides. Malathion and propanil were estimated to have half-lives on the order of 1 to 2 days in the stream, whereas others (atrazine, lindane, and terbacil) were estimated to have half-lives on the order of 1 to 3 years.

Stream observations of LAPU

The results of the simple modelling of percent lost in a 15 day travel time (Table I) are in agreement with actual observations of LAPU in the streams. Metolachlor and trifluralin are used as examples of two types of behaviour in Figure 2. Metolachlor is used as an example of those compounds that have minimal in-stream loss. Trifluralin is used as an example of those compounds that have substantial in-stream loss. All of the LAPUs for metolachlor and trifluralin, from both field runoff and stream observations, have been combined in Figure 2. There are 278 LAPU values for metolachlor and 105 LAPU values for trifluralin. Although, for a given watershed area, there is substantial variation in the log LAPU values for both metolachlor and trifluralin because of differences in rainfall or irrigation and terrestrial conditions (Capel and Larson, 2000), the overall relations between LAPU and watershed area are different for the two compounds. Metolachlor has the same range of LAPU values throughout the range of scale. On the basis of an ANOVA test, the mean LAPU values

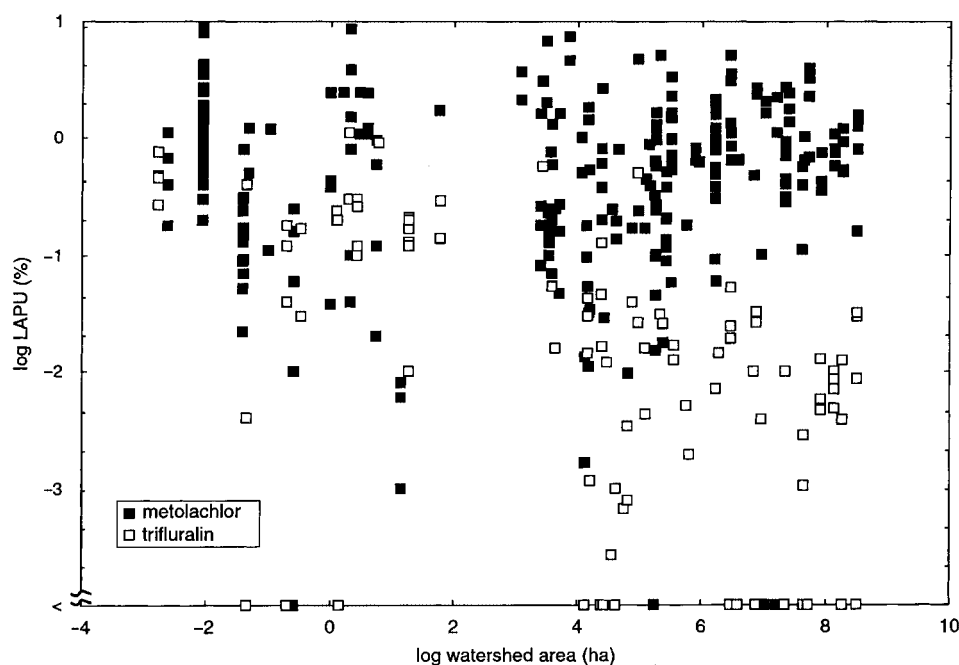


Figure 2. log LAPU (%) as a function of log watershed area (ha) for two herbicides, metolachlor and trifluralin. Data reported for watershed areas < log 2 ha are from field-based studies. Data reported for watershed areas > log 2 ha are from stream-based studies

do not vary among field plots (<60 ha) and small ($<10^5$ ha), medium (10^5 to 10^7 ha), or large ($>10^7$ ha) watersheds ($p = 0.66$). Also, the slope of the regression line of log LAPU versus log area is essentially zero (0.0033). These two observations suggest strongly that the LAPU values observed in field runoff are in the same range as the LAPU values determined from stream loads and that a minimal amount of metolachlor is lost through in-stream processes. The latter observation is consistent with the prediction reported in Table I. On the other hand, the trend in the LAPU values, as a function of watershed area, is different for trifluralin than for metolachlor. The field-scale ($<10^2$ ha) observations of log LAPU have little relation with log area, but are statistically different from the LAPUs observed in the streams (Table II, $p < 0.001$). The stream observations of LAPU show a trend of decreasing LAPUs with increasing watershed area (Table II). The trend in the observed LAPUs is consistent with the prediction reported in Table I of substantial loss of trifluralin from the stream due to volatilization.

On the basis of the observed LAPUs as a function of watershed area, the behaviour of the 39 pesticides quantified by the NASQAN and NAWQA program fall into three general groups. The first group consists of pesticides that were seldom seen in surface water (Table II). The compounds in this group have low-use amounts (lindane, permethrin, and pronamide, Table I), use only in limited geographical areas (DCPA, ethalfuralin, molinate, pebulate, and thiobencarb), short soil lifetimes (disulfoton, malathion, and parathion), short aquatic lifetimes (propanil and terbufos) and (or) use practices that diminish the chance of runoff, such as soil incorporation (benfluralin, napropamide, and terbufos) or application late in summer when little rain-producing runoff occurs (disulfoton and malathion). Not much information about the behaviour of these compounds can be gleaned from these data, except that their relative absence from the water can be explained, for the most part, on the basis of use, application practice, or relatively fast loss from soil and (or) water. Phorate is the one exception. It was not observed in any of the basins that meet the minimum use criteria, but has relatively high use (ranked 34th nationally in use), is commonly applied at the soil surface, and is estimated to have a relatively low in-stream loss rate (Table I). It is often applied in granular form, so it may not be as available for transport in runoff.

The second group includes those compounds that show little, if any, loss within the stream network. This can be quantified by comparing the LAPU values observed for streams draining smaller watersheds ($<10^5$ ha) and LAPU values for larger watersheds ($>10^7$ ha). Because the actual travel times of the pesticides in the streams are unknown, watershed area is used as a surrogate for travel time. Alachlor, atrazine, cyanazine, diazinon, metolachlor, metribuzin, propachlor, and simazine have mean stream LAPU values that differ by less than a factor of two, suggesting that there is relatively little in-stream loss of these compounds. This agrees very well with the results for the simple model predictions, which suggest that these eight compounds have relatively small in-stream losses ($<37\%$) in a 15 day travel time (Table I). Three other compounds, predicted to have this same range of loss from surface water, are not included in this list of eight. These three are ethoprop, lindane, and terbacil. Lindane and terbacil have very low use amounts and are seldom detected in surface waters, so their losses cannot be explained using these data. Ethoprop meets the minimum use criteria in 16 studies, but only seven LAPU values could be calculated, which means that it was also observed infrequently in the streams. This may be due to a combination of relatively low use (ranked 67th in use) and a low potential for transport in runoff (median LAPU value: 0.0080% for watersheds $> 100\,000$ ha). It was observed at low concentrations in the small watersheds, but never quantified in the larger watersheds. This probably is due to dilution, yielding concentrations below the detection limit, rather than in-stream losses, but there is not enough data available to say this conclusively.

The third group consists of those compounds that have a difference in the mean LAPU values greater than a factor of two between the two watershed sizes. In all cases, the LAPU values for the larger watersheds are smaller than the LAPU values for the smaller watersheds. This suggests strongly that there is in-stream loss occurring for these compounds. Because these compounds were observed in the smaller watersheds, the pesticides did move off the fields and into the stream, but a substantial fraction (on average 50 to 100%) was lost during transport in the stream. This group of compounds includes azinphos-methyl, butylate,

carbaryl, carbofuran, EPTC, ethoprop, fonofos, linuron, methyl parathion, pendimethalin, propargite, triallate, and trifluralin.

Another way to divide the selected pesticides is by type and application method: surface-applied herbicides, incorporated herbicides, and insecticides (Table I). On the basis of an ANOVA test, the surface-applied herbicides have significantly greater mean LAPU values in all three categories of watershed area ($<10^5$, 10^5-10^7 , and $>10^7$ ha, $p < 0.001$ for all three) compared with the incorporated herbicides and insecticides. This is in agreement with the findings from the field runoff studies.

When the LAPU values are compared among the three categories of watershed area, the incorporated herbicides had significantly greater LAPU values in the small watersheds ($<10^5$ ha) than in the largest watersheds ($>10^7$ ha). This is in agreement with loss estimates reported in Table I, where all of the incorporated herbicides had estimated in-stream losses $\geq 70\%$, except for triallate. In contrast, there is no significant difference in the LAPUs for the surface-applied herbicides among the watershed area categories. This is also consistent with the model predictions. All seven surface-applied herbicides that were frequently observed (alachlor, atrazine, cyanazine, metolachlor, metribuzin, propachlor, and simazine) had estimated in-stream losses $\leq 40\%$. Finally, there was also no significant difference in the LAPUs for the insecticides, even though the 16 insecticides included in this study have a wide range of estimated in-stream losses (14 to 99%).

Median small-scale LAPU values

The median small-scale LAPU is a measure of the central tendency of the LAPUs of an individual pesticide across a variety of environmental conditions and watershed areas (Table II). The variability around this central tendency is illustrated in Figure 3 for five example herbicides. The median small-scale LAPU is calculated as the median LAPU values for the field studies and the small watershed studies ($<100\,000$ ha). Data from only field and small watershed studies ($<100\,000$ ha) were used to minimize the bias from in-stream losses. A LAPU value of zero was substituted for any ' $<$ ' in the calculation. Thiobencarb had no measurements of

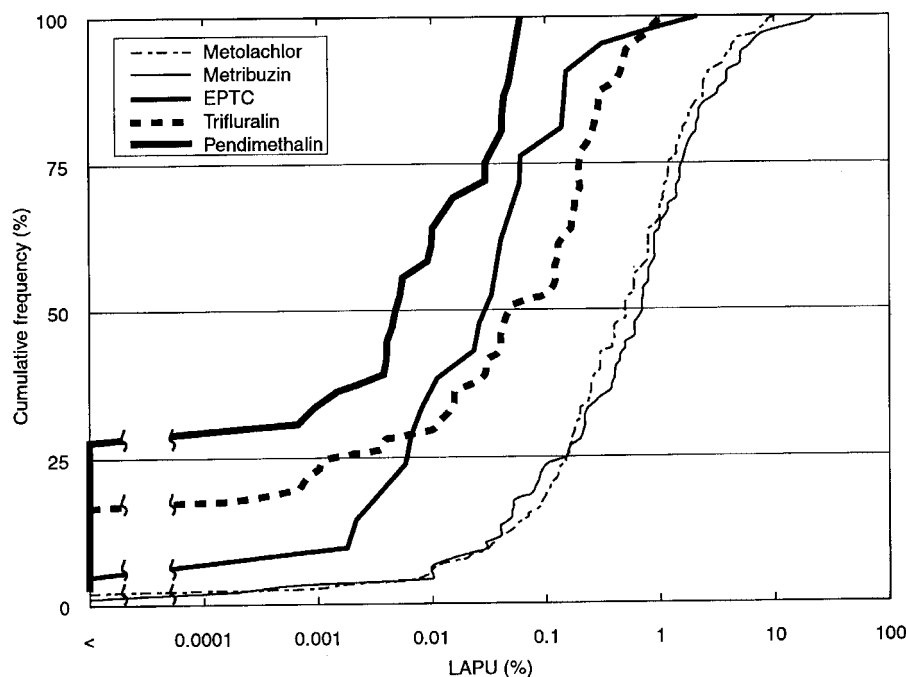


Figure 3. Cumulative frequency diagram of the LAPUs for five herbicides from studies of fields and study plots (<100 ha) and small watersheds ($101-100\,000$ ha)

LAPU in either fields or streams, so no median small-scale LAPU value is reported. Pronamide, propanil, and terbacil had only one watershed observation of LAPU, so was not included in the following discussion.

Three pesticides—DCPA, napropamide, and molinate—had median small-scale LAPU values greater than 1%. Because these three compounds had only a few measured LAPU values, their median small-scale values reported in Table II have a high degree of uncertainty. If the median small-scale LAPUs are ranked for the herbicides, the incorporated herbicides generally have smaller values, and the surface-applied herbicides the larger values. The mean LAPU values for the surface-applied herbicides, incorporated herbicides, and insecticides, are compared in Table II. The median of the median small-scale LAPUs is also much greater for the surface-applied herbicides (0.5%) than the incorporated herbicides (0.0031%). Pendimethalin, a surface-applied corn herbicide, has a much lower median small-scale LAPU compared with the other surface-applied herbicides. It also has a much greater tendency to sorb, as quantified by its $\log K_{oc}$ value (Table 1), than the other surface-applied herbicides. Because of the stronger sorption tendencies, the runoff of particles may control the extent of pendimethalin's runoff, whereas the runoff of water may control the extent of runoff of the other more water-soluble surface-applied herbicides.

DISCUSSION

Many factors influence the behaviour of a pesticide from the time of its application to an agricultural field to the time that it is delivered to the ocean. Figure 4 attempts to capture, in a generic manner, the range of behaviour across this range of scale. The axes of Figure 4 are the log of watershed area (to represent scale effects and riverine travel time) *vs* the log of LAPU. This allows both an easy compound-to-compound comparison and a watershed-to-watershed comparison for the same compound, because it normalizes for the amount of use. The vertical line in the figure represents the transition between agricultural field and first-order stream (or drainage ditch). This is the scale at which the pesticide runs off the field and enters the riverine network. The behaviour of five different generic pesticides, denoted A, B, C, D, and E, is plotted, and will be described individually. There are additional details drawn for compound 'A' that are applicable to the other compounds, but not included for the sake of simplicity.

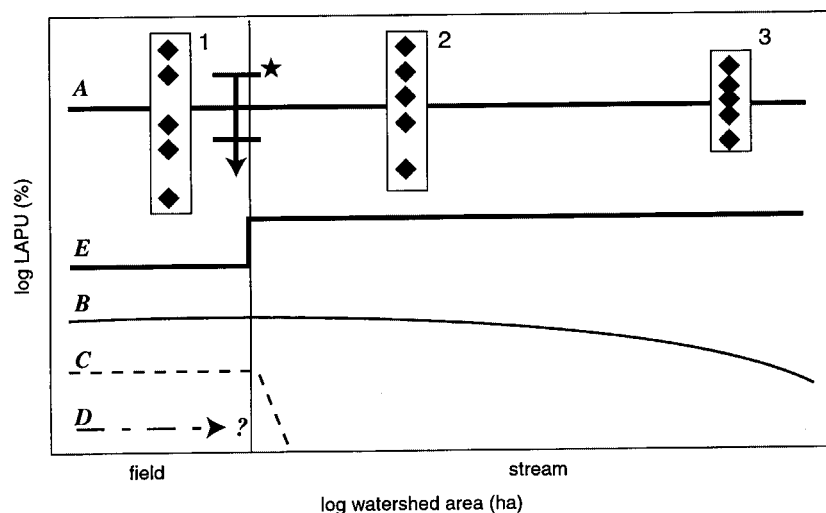


Figure 4. Cartoon of the apparent LAPU value of five generic pesticides (A–E) in their field runoff and surface water transport as a function of scale. Boxes 1–3 represent the year-to-year variability at a given site. The star represents the range of variability in the LAPU for the various terrestrial environments. The median small-scale LAPU for compounds B and C could be anywhere on the y-axis. This cartoon just demonstrates their relative in-stream behaviour. Based on field observations, the scale of the y-axis (log LAPU in percent) is generally between -4 and 1 (0.0001 and 10%)

The median small-scale LAPU value for a given pesticide is partially controlled by the combination of its application method, formulation, and chemical properties (Capel and Larson, 2000). These three are somewhat interrelated. The variability around the median small-scale LAPU is due to the natural terrestrial environment (soil, slope, etc.) and the standard management practices (tillage, crop, etc.) for that pesticide. In Figure 4, the 'I-beam' at the star represents this variability around the median small-scale LAPU value. Capel and Larson (2000) showed that the median small-scale LAPU value for atrazine was 0.66% and that the central tendency was relatively constant from data collected in watersheds that ranged over 14 orders of magnitude in area. They also showed that part of the variability in the LAPU values for atrazine could be related to the extent of water yield during the period corresponding to the period of maximum atrazine runoff.

The arrow at the bottom of the 'I-beam' (Figure 4 at the star) represents the desired impact of BMPs on pesticide runoff. That is, the implementation of BMPs is supposed to reduce LAPU values. BMPs can be implemented through landscape modifications (i.e. vegetative buffer strips), conservation tillage methods, decreased use of pesticides, and (or) method of application. The first two groups of BMPs, although very important, would most likely decrease the median small-scale LAPU of water-soluble pesticides only slightly. The impact of these types of BMP would probably be measured as part of the inherent variability in the chemical's LAPU value. In Figure 4, this would have the effect of extending the lower portion of the 'I-beam'. On the other hand, decreased use or changes in the application method have the potential for a more significant impact. As an example, if the application method of a herbicide, such as atrazine, is changed from surface-applied to incorporated, its runoff behaviour might be characterized as changing from compound A to compound B in Figure 4.

The numbered boxes represent the year-to-year variability because of weather (or excess irrigation) that can be expected at different points in the range of scale (Capel and Larson, 2000). At the field scale (Figure 4, box 1), the variability is very high because of the influence of individual storms. As observed in many plot studies (Leonard, 1990), it is often the intensity and timing of rainfall with respect to application that determines the extent of runoff of the pesticide for any given year. This year-to-year variability decreases somewhat at the small watershed scale that integrates runoff from tens to hundreds of farm fields (Figure 4, box 2). There will still be years that are 'outliers', compared with the long-term average, caused by drought or very large storms that produce runoff for numerous fields at the wrong time with respect to pesticide application. This was observed with atrazine in the Sugar Creek watershed in Indiana (area: 24 600 ha), where the LAPU values for the 6 years 1993–1998 were 1.3%, 0.80%, 0.82%, 2.2%, 14%, and 2.3% respectively. The year that had a LAPU of 14% had an unexpected storm that came soon after the time of atrazine application (Capel and Larson, 2000). At the largest scale (major rivers, Figure 4, box 3), the year-to-year variability will be less, because of the integration of the runoff from thousands of agricultural fields over a very large area. The timing of application in these large watersheds for any given compound may vary by weeks because of climate differences. There seldom will be weather patterns that would affect the runoff in a large enough area to affect strongly the LAPU observed in the largest rivers.

The differences in the generalized behaviour of each of the representative compounds can be considered. Compound A has a relatively high LAPU value that is constant over the range of scale. This means that a substantial percentage of the amount applied is lost in runoff from the field and that there is little loss within the riverine network. This is the behaviour observed for atrazine, described in detail in Capel and Larson (2000), as well as metolachlor (Figure 2) and alachlor and cyanazine (Table II). The compounds in this group are the pesticides that are most frequently detected and exhibit seasonally elevated concentrations in rivers and streams over the complete range of scale (Larson *et al.*, 1999).

Compound B is representative of a pesticide that has moderate in-stream losses. Because the median small-scale LAPU is determined by the chemical, its formulation, and application method, it can fall anywhere in the range of median small-scale LAPU values. The difference in compound B, compared with compound A, is its accelerated rate of loss in the riverine system. Examples of compound B would be EPTC, trifluralin (Figure 2), and other pesticides in Table II that have losses in the range of 20 to 90% for the example 15 day travel time. These compounds are expected to be seen more frequently and at higher concentrations in small

streams compared with the larger rivers. Because their observed LAPUs will decrease as a function of travel time in the river (Table 2), the extrapolation of stream observations back to field runoff must be done with great caution.

Compound C is similar to compound B, except that its riverine loss processes are much faster. Examples of these compounds include azinphos-methyl, ethalfluralin, malathion, pebulate, and terbufos (Table II). They are seldom detected in surface waters removed from direct agricultural runoff (Larson *et al.*, 1999).

Compound D is representative of those compounds that have very short lifetimes (days) in the soil that are seldom seen in field runoff, such as propachlor and propanil. These compounds are also seldom detected in surface waters (Larson *et al.*, 1999).

Finally, compound E is representative of those compounds that have incorrect (artificially high) LAPU values in watersheds. These pesticides, such as diazinon and simazine, have other substantial uses, in addition to agriculture, that act as sources to the environment. Because the LAPU value defined here is based on agricultural usage (Gianessi and Anderson, 1996), the LAPU value observed in some watersheds will be artificially high. In the USA, diazinon is often observed in surface waters in the Pacific coast states, in the Midwest, and in urban streams (Larson *et al.*, 1999; Hoffman *et al.*, 2000). Diazinon is frequently used in orchards in the West; therefore, some of the soil degradation processes could be by-passed in its transport from tree to stream. Diazinon also has wide-scale home and garden uses in urban areas. Larson *et al.* (1995) have suggested, on the basis of the temporal concentration patterns in the White, Ohio, and Mississippi Rivers, that the dominant source of diazinon to these rivers is urban rather than agricultural.

One goal of agricultural and regulatory managers is to reduce the amount of pesticides that get into, and are transported through, surface waters to minimize the potential impact on the biological community. On the basis of Figure 4, this can be achieved by decreasing the LAPU of current pesticides through BMPs, particularly the application method, or by creating new compounds that are quickly lost in the soil or water and, thus, have small LAPU values. Both of these methods are being used to reduce the load of pesticides in surface waters. Historically, there has been a move to less persistent pesticides (i.e. DDT to organophosphates). There also has been an increase of BMPs to control runoff (i.e. conservation tillage, buffer strips, and contour ploughing). The use of precision agriculture may be used to decrease the amounts of pesticides used on a field and decrease the pesticide load in runoff. Perhaps one of the simplest and most effective BMPs (based on the findings of this study) would be changing the method of application and formulation, when it is possible. There could be a substantial reduction in the amount of herbicides delivered to surface waters if there was a move away from surface application. Of course, such a change must balance considerations of efficacy, crop toxicity, and chemical properties against a decrease in the amount of the herbicide in runoff and the concomitant change in its impact on the health of aquatic ecosystems and humans, and the increased potential for the contamination of ground water.

A pesticide concentration or load in a given stream is the result of the combined processes that affect the extent of runoff and the extent of in-stream losses. To understand properly and characterize its behaviour, both of these sets of processes must be considered together. For atrazine, Capel and Larson (2000) showed that the observations of LAPU in streams across the complete spectrum of scale could be extrapolated back to the extent of field runoff. That is, the LAPU values measured in field runoff were not significantly different from those measured in streams. This same behaviour can be seen for metolachlor in Figure 2. In fact, all of the pesticide included in this study (with sufficient observations to evaluate) had the same range of LAPUs in the smallest streams as in field runoff studies. For many of these compounds, the observed LAPU decreased or went to zero in the larger streams. These observations point to three important components of pesticide behaviour that must be considered when interpreting monitoring data and making regulatory decisions. First, the results of field runoff studies are directly applicable to estimating the amounts of pesticides delivered to surface water systems. Second, many pesticides are lost within the surface water system, some quite quickly. Therefore, infrequent detection of individual pesticides in streams does not necessarily mean that they were not initially delivered from the field to the stream. Third, each pesticide is a different organic chemical and,

thus, will behave uniquely with respect to its environmental transport, fate, and effect on human and ecosystem health.

The concern over the occurrence of pesticides in surface waters is largely driven by their potential impacts on human and ecosystem health. In many ways, the concerns change as a function of stream size. In smaller streams, the focus of concern is on ecosystem health. Smaller streams make up the majority of riverine miles and provide important habitat for reproduction of aquatic organisms. There are relatively few public drinking water intakes on very small streams. The concern in larger streams and rivers focuses more on human health because they more commonly serve as sources of drinking water. The larger streams also tend to have numerous perturbations (industrial chemical inputs, thermal inputs, dredging, etc.) that have permanently changed the natural ecosystem. Although the impact of pesticides in large rivers may still be important, it is only one of many potential impacts on their ecosystems. (The exceptions to this are the persistent, organochlorine insecticides that readily bioaccumulate. They are of concern to both human and ecosystem health throughout the entire spectrum of watershed areas.) Given these changing concerns with stream size, it should be reiterated that each pesticide is a different organic chemical and, thus, will behave uniquely in its environmental transport, fate, and effect on human and ecosystem health. Only through detailed runoff studies and broad-scale stream monitoring, in conjunction with insights provided by process-based models, can the behaviour of individual pesticides be characterized to the extent that is needed to interpret monitoring results fully and make regulatory decisions.

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From: Pease, Anita
To: cathy.tortorici@noaa.gov
Cc: [Guilaran, Yu-Ting](#); [Goodis, Michael](#); [Richard, Keigwin](#); [Cowles, James](#); [Dyner, Mark](#); [Rimmer, Leigh](#); gina_shultz@fws.gov; [Aubrey, Craig](#); [Kunickis, Sheryl - OSEC](#)
Subject: EPA's consolidated comments on the second ESA Report to Congress
Date: Monday, May 23, 2016 3:52:42 PM
Attachments: [General Comments to Address.docx](#)
[ESA Report to Congress Combined Comments EPA.docx](#)

Cathy,

Please see attached EPA's consolidated general and specific comments on the second Report to Congress. Thanks.

Anita Pease
Acting Director
Environmental Fate and Effects Division
U.S. EPA Office of Pesticide Programs
703-305-0392
pease.anita@epa.gov

General Comments to Address:

From Mark Dynner:

I agree with everything Rick says below and with all his comments in the document. I tried in some places to provide suggestions for how the report might at least marginally address all the elements for the second report identified in section 100013 of the 2014 Farm Bill and the portions of the conference committee report addressing that section (which appears to tack on some additional elements). To be clear, my suggestions are not calculated to turn this into a “good” product, but rather to at least minimally meet the congressional directives for the report. But I think you all need to decide with the Services how you feel about submitting a marginal product to the Hill and whether it makes sense to undertake a more substantial rewrite.

From Richard Keigwin:

- There is a lot of repetition across the report, and yet, similar situations/accomplishments/issues are described differently.
- I’m not sure this report addresses all of the requirements for the 2nd Report to Congress. Specifically, the Farm Bill and the Managers Report talk about the 2nd report needing to, among other things:
 - Update the study and report required by subsections (b) and (c) of section 1010 of Public Law 100-478.
 - Discussion of how the Services are exploring how habitat conservation plans could be employed as part of an Incidental Take Permit
 - Provide a schedule for the initiation and completion of future consultations
 - Recognize EPA’s obligations to meet statutory timeframes under FIFRA Sections 3 and 33
 - Discuss the resource available to the Services to address pesticide-related consultations
 - How the vacatur of the counterpart regulations has been overcome

For more information, see pages numbered 1098 through 1100 (pages 149-151 of the PDF) of the Statement of Managers, available at: <http://www.agriculture.senate.gov/imo/media/doc/SOMandEarmarkFINAL.pdf>.

And, here’s a link to the Farm Bill (see pages 303 and 304):

http://www.agriculture.senate.gov/imo/media/doc/Farm_Bill_Final.pdf.

From James Cowles:

I think this report is an optimistic presentation of where EPA and the Services are in implementing the NAS report and finding a viable path forward that allows EPA to meet its obligations under FIFRA Sections 3 and 33. Currently, the report presents the successes we have had but is silent on the significant challenges that remain. For example:

- Although there has been much progress we should indicate the current process for Steps 1 and 2 is not sustainable given the resources allocated.
- It is unclear at this time whether or not the Services will be able to complete Step 3 in a timely manner.
- There remain technical matters for which we have not been able to reach consensus
 - e.g., modeling approaches and the use of monitoring data
- A majority of species lack sub county species range maps

I suggest a section be added that discusses the remaining challenges facing EPA and the Services. Several of Rick’s bullets would fit under this section as well.

DRAFT

**Final Report to Congress
Endangered Species Act Implementation in
Pesticide Evaluation Programs**

May 2016



**Prepared by the U.S. Environmental Protection Agency,
National Marine Fisheries Service,
U.S. Fish and Wildlife Service, and
U.S. Department of Agriculture**

Purpose of this Report to Congress

The National Academy of Sciences' (NAS) National Research Council (NRC) report, entitled "Assessing Risks to Endangered and Threatened Species from Pesticides" (NAS NRC report) was released on April 30, 2013. The report contained recommendations on scientific and technical issues related to pesticide consultations under the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since then, the Environmental Protection Agency (EPA), the National Marine Fisheries Service (NMFS) and the Fish and Wildlife Service (FWS) (the Agencies) have worked to implement the recommendations.

On February 7, 2014, President Obama signed into law the Agricultural Act of 2014 (P.L. 113-79). As provided in Section 10013 of Title X - Horticulture, on the ESA Implementation in Pesticide Evaluation Programs, Congress required this final report to be delivered one year after the Bill was signed into law. The intent expressed in this provision is to keep the Agencies moving forward as they develop processes that will make it possible to utilize the necessary resources to complete Biological Evaluations and Biological Opinions as part of pesticide consultations, and minimize delays of pesticide registration and registration review decisions under FIFRA. In addition, the provision is intended to encourage meaningful public participation, and reemphasize that all ESA-mandated Reasonable and Prudent Alternatives (RPA) are technologically and economically feasible, that ESA-mandated Reasonable and Prudent Measures (RPM) are necessary and appropriate, and that the Agencies have ensured public participation and transparency in the development of Biological Evaluations and Biological Opinions RPAs and RPMs, where appropriate. In response to the Agricultural Act of 2014, this final Report to Congress identifies specific actions that have been and will be taken to address the recommendations of the 2013, NAS NRC report and evaluates current and planned approaches to establish that:

- The Agencies utilize the best available science;
- RPAs -will be technologically and economically feasible;
- RPMs will be necessary and appropriate; and
- The Agencies will ensure public participation and transparency in developing RPAs and RPMs.

This final Report to Congress addresses [the Agencies' efforts with respect to each of these elements these four recommendations](#) as required by Congress [and also serves as an update of the study and report required by subsection \(b\) and \(c\) of section 1010 of Public Law 100-478 \(7 U.S.C. 136a note\)](#). The final Report to Congress also builds upon the November, 2014 interim Report to Congress that described the approaches and actions taken to ensure public participation and transparency during implementation of the recommendations from the NAS NRC's study and minimize delays in integrating applicable pesticide registration and registration review requirements with species and habitat protections.

Important Progress and Next Steps

Commented [DM1]: Not really sure these are best described as recommendations. The NRC report included recommendations, but Congress directed a report that described our efforts to achieve each of the four bulleted elements. That sounds like something more than a recommendation

Commented [DM2]: This is a required element as well.

In addition, as Rick pointed out in his email, in interpreting the requirements of the farm bill, the conference committee report appears to expand upon the elements that the Agencies should discuss. While I would not highlight those here as distinct "required" elements, I think to be fully responsive to the committee, the report should weave in language that addresses those points. I'm not sure that necessarily requires much more than explaining how what we're doing through the implementation of the NAS report helps to accomplish those ends. With that said, I'm not sure what if anything anyone has done to evaluate whether there are HCP's developed for section 10 permits that could be used to simplify the section 7 process. So I'm not sure what you all can say about that element from the committee report.

The Agencies have made significant strides to further the development of a robust set of ESA consultation documents that include joint Agency collaboration and stakeholder involvement. We solidified the technical analyses and processes to produce Biological Evaluations and eventually Biological Opinions that are scientifically credible, legally defensible, and take into account the concerns and advice voiced by key stakeholders. As a result of the ongoing collaborative efforts, the Agencies moved forward with applying the NAS NRC interim report approaches to pesticide consultations, have completed some consultations affording species protections, and developed work products that describe changes to processes intended to streamline consultations and provide ample opportunity for stakeholder engagement. We go into more detail later in this report on specific Major Accomplishments section on page 16 of this report. Progress to date includes:

- Established a long-lasting and collaborative relationship on the ESA consultation process between the Agencies, with the assistance of the USDA;
- Modified the traditional ESA consultation process for Biological Opinion development to allow for interagency review, comment and participation in the process;
- Clarified the roles and responsibilities for the Agencies and USDA to improve agency processes that enhance stakeholder engagement and transparency during ESA consultation process;
- Conducted four joint Agency workshops resulting in NAS NRC report interim approaches to assessing risks to ESA-listed species from pesticides;
- Implementing a plan and schedule for applying the NAS NRC report interim approaches to an initial set of pesticide compounds;
- Conducted four stakeholder workshops and meetings to seek input and improve transparency as the ESA consultation process evolves; and
- Released the first round of draft Biological Evaluation sections and provisional models for chlorpyrifos, diazinon, and malathion in December 2015. This information can be found at: (<http://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and>).

Commented [DM3]: Verb form agreement issue here. Should probably say "Establishing/Modifying/Clarifying etc."

Commented [KR4]: Shouldn't we add the release of the draft BEs in April 2016?

Important Next Steps include:

- Looking for Process Efficiencies – The Agencies engaged the facilitation group *Resolve* to conduct a retrospective review of our work by soliciting ideas from senior managers and scientists working on the three pilot chemical consultations to answer the question, "What efficiencies or improvements can we incorporate into the "no effect/may affect" determinations made in Steps 1 and 2 moving forward based on lessons learned from the interagency work thus far?" The Agencies established a workgroup to refine these recommendations and incorporate responses to the efficiencies recommendations provided by Croplife America and the Minor Crop Farmer Alliance to the Agencies on

Commented [DM5]: Here's one place where you might want to specifically link this effort to an element of the report requirement – e.g. – "These efforts will help EPA to timely meet its FIFRA obligations while making the most efficient use of Service consultation resources."

January 21, 2016. The workgroup's goal is to develop a set of recommendations to build into the next round of Biological Evaluation development.

Commented [KR6]: Do we need to define what we mean by "next round" or should we just say "future"?

- Biological Evaluations –

- The first round of draft Biological Evaluation sections and provisional models for the three pilot chemicals, chlorpyrifos, diazinon, and malathion, were released for public review as an early on look at analyses in the documents in December, 2015.
- The completed draft Biological Evaluations were released for an extended, 60 day public comment in April, 2016.
- The Agencies presented a public webinar on May 5, 2016, the Biological Evaluations to review major analyses, conclusions, and answer questions.
- The proposed date for the final nationwide Biological Evaluations will be around December, 2016. The final completion date is contingent on the number of comments received during the public comment period.
- The NMFS and FWS draft Biological Opinions are proposed to be completed by the end of 2016.
- The final nationwide Biological Opinions are scheduled for release in 2017.
- Concurrent with the work on these documents in 2016 on these three pilot chemicals, the Agencies began development of the draft Biological Evaluations for the next two chemicals, carbaryl and methomyl, with an anticipated release date by the end of 2016.

Commented [KR7]: Why do we say "extended"? Our typical process for draft risk assessments in registration review is to have a 60-day comment period (albeit the regs say we can limit to 30 days)

Commented [KR8]: A word seems to be missing here

Commented [KR9]: What if we just said that we anticipate completing the final BEs in December 2016, but then provide the caveats discussed in the 2nd sentence.

Commented [KR10]: So, the draft BiOps will be available at the same time as the final BEs?

Also, should we mention, consistent with the transparency paper, that we will seek public comment on the draft BiOps?

Commented [KR11]: For chlorpyrifos, diazinon, and malathion. Shouldn't we say that they are scheduled to be completed by the end of 2017?

- Proposed Stakeholder Workshop – The Agencies, in conjunction with a steering committee composed of Agency, industry representatives and non-governmental organizations will plan and host a 2-day workshop in late summer, 2016 to discuss potential refinements to the interim scientific methods and Biological Evaluations developed to assess pesticide risks to ESA-listed species and designated critical habitat.
- Out Year Planning - The Agencies are also working on developing a workplan for out-year planning for biological opinion development beyond 2022.

Legal Framework for EPA, NMFS, and FWS

EPA regulates the distribution, sale, and use of pesticides under FIFRA. Under Section 3 of FIFRA, subject to limited exceptions, a pesticide must be registered by the EPA prior to its distribution or sale. Before EPA may register a pesticide under FIFRA, the applicant must show,

among other things that using the pesticide according to specifications “will not generally cause unreasonable adverse effects on the environment.”¹

If EPA concludes that the pesticide, together with its accompanying labeling and any terms and conditions, will not cause unreasonable adverse effects on the environment, EPA grants the registration and the labeling provisions approved by EPA become the enforceable use directions for the pesticide product. Post-registration, EPA reviews and re-evaluates a pesticide every 15 years as part of registration review to determine whether it continues to meet the FIFRA registration standard.² EPA used the registration review process to address its ESA obligations for pesticide registrations through the continued development of nationwide effects determinations.

Under section 7(a)(2) of the ESA, all federal agencies have responsibility to insure that any action authorized, funded, or carried out by that agency is not likely to jeopardize the continued existence of any federally listed endangered or threatened species (ESA-listed species), or result in the destruction/adverse modification of designated critical habitat. Therefore, under ESA, EPA must insure that its activities in administering FIFRA are not likely to jeopardize the continued existence of any federally ESA-listed species or adversely modify/destroy their designated critical habitat.

Regulations implementing Section 7 of the ESA require that federal agencies initiate “consultation” with NMFS and FWS on certain actions that “may affect” ESA-listed species or designated critical habitat. The extent to which NMFS and FWS are involved in the consultation depend on the agency’s action, the ESA-listed species potentially affected by that action, and the Service responsible for administering consultations for the listed species potentially affected. NMFS and FWS conclude a formal consultation by issuing a Biological Opinion that addresses the proposed federal agency action considered during consultation. NMFS and FWS determine whether the proposed action assessed in the Biological Opinion is likely to jeopardize the continued existence of an ESA-listed species, or adversely modify/destroy designated critical habitat. If the FWS, or NMFS, determines from its assessment that a proposed action is likely to jeopardize the continued existence of the species, or adversely modify/destroy designated critical

¹ FIFRA defines the term “unreasonable adverse effects on the environment” to mean: “(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act.”

² Due to concerns that much of the safety data underlying pesticide registrations becomes outdated and inadequate, FIFRA Section 4 requires that registrations be reviewed every 15 years and requires EPA to re-evaluate all pesticides that were registered before 1984. The goal is to update labeling and use requirements and reduce potential risks associated with older pesticide active ingredients -- those first registered when the standards for government approval were less stringent than they are today. This comprehensive reevaluation of pesticide safety in light of current standards is critical to protecting human health and the environment. [This note conflates the requirements of section 4 (reregistration) and section 3(g) (registration review). Reregistration applied only to the post 11/84 pesticides and was a one time review. Registration review under 3(g) applies to all pesticides and creates a continual 15-year review cycle for pesticides to ensure they meet the statutory standard. But I really don't think you need this footnote at all because the text sufficiently covers what that review is all about.]

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habitat, it must provide the federal agency with draft RPAs to the action, if those exist for review by the federal action agency.

If NMFS or FWS concludes that take of the species (*i.e.*, harass, harm³, pursue, hunt, shoot, wound, kill, trap, capture, or collect any threatened or endangered species) will not violate ESA section 7(a)(2), NMFS and FWS provide the federal agency with an incidental take statement. The incidental take statement identifies the amount or extent of incidental take exempted for the proposed action, along with RPMs that minimize the impact of take, and implementing terms and conditions. Incidental take that occurs when the agency action is conducted in compliance with the implementing terms and conditions is exempt from statutory or regulatory prohibitions of take that would otherwise apply.

While USDA does not have a formal role in the ESA consultation process between EPA (the action agency), NMFS and FWS, they do play an important role to provide the Agencies pesticide use and usage data, and information on agricultural production practices. In addition, the USDA's National Agricultural Statistics Service (NASS) provided assistance on the appropriate use of the Cropland Data Layer (CDL) and other geospatial information related to the location of agricultural crops.

Approach to Minimizing Litigation on the Agencies Joint-Pesticides Work

In the interest of minimizing litigation and addressing plaintiffs concerns, EPA dialogued with the litigants and implemented a 3-pronged strategy that is intended to address effects to ESA-listed species and designated critical habitat by focusing resources on areas where we can achieve the most protections.

First, EPA focused the majority of its ESA consultation work through registration review. This allowed EPA to focus on chemicals with higher risk, *i.e.*, the "worst first," resulting in the greatest potential benefits for ESA-listed species while addressing litigant concerns. Consistent with the interagency "shared scientific approaches" and "day forward approach," the Agencies implemented the interim scientific measures to the three pilot chemical consultations. The goal of this approach continues to be to gain experience and refine these approaches as the consultation process continues with future chemicals.

Second, EPA completed an Overview Document-compliant endangered species assessments for new herbicide tolerant crop uses. An assessment that is Overview Document-compliant followed the procedures and methods described in the Overview Document. The Overview Document formed the basis for all ecological assessments for all chemicals other than chlorpyrifos, diazinon, malathion, carbaryl, and methomyl. EPA will complete these effect determinations as resources allow. To maximize impact within these resources, it is likely that the initial registrations will not be nationwide in scope, and to the extent practical will focus on situations where EPA can make "no-effect" decisions. The Overview Document can be found at the

Commented [KR12]: Shouldn't there be a possessive here?

Commented [KR13]: This suggests that the litigants helped us develop the 3-pronged strategy. I think that is inaccurate.

Commented [DM14R13]: I agree with Rick. We entered into settlement and revised settlements that allowed us to focus on NAS implementation on the 5 pilots rather than addressing near-term consultation deadlines, but we did not "dialogue" with litigants on the three-pronged strategy.

Commented [KR15]: Should this say "is focusing"?

Commented [KR16]: Need to convey that this is our plan for all HTC registrations moving forward, so I'm not sure that using the past tense here is appropriate.

Commented [KR17]: What are we trying to convey?

Commented [KR18]: What are we trying to convey?

Commented [DM19]: I agree with Rick. Without any context, no one will have any idea what the point is here and what it is doing in a section about minimizing litigation risk. Actually, why do we have that title, given that it really doesn't directly relate to the report requirements? This section is more about EPA's plans to timely address its ESA and FIFRA obligations in a way that will make the best use of its and the Services' limited resources.

³ Harm is further defined in 50 CFR Part 222

following link: <https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf>

Third, ~~for new active ingredients~~, EPA will ~~continue to provide information that compares~~ compare the potential hazards of the new active ingredients to already registered pesticides ~~with similar modes of toxicity and the same use patterns~~. This will allow stakeholders to compare the relative toxicity of the proposed registration to available alternatives. EPA believes that older, currently registered chemicals typically have the potential to pose greater risks to ESA-listed species than do the newer, generally ~~safer-lower-risk~~ pesticides being introduced into the marketplace today, and that the comparative hazard information will illustrate this to all stakeholders. This additional hazard information ~~contributed~~ contributes to information sharing, ~~promoted~~ promotes communication with the public, and ~~improved~~ improves relationships and trust with stakeholders.

Commented [KR20]: Don't we mean the registered alternatives to the proposed registration?

Commented [KR21]: We try to avoid using the term "safer"

Litigation Status

~~The litigants that are actively suing the Agencies over ESA compliance of pesticides registration (i.e., Northwest Center for Alternatives to Pesticides [NCAP] and the Center for Biological Diversity [CBD]) understand that the Agencies have limited resources and that responding to litigation diverts technical staff from completing the ESA national level consultation process. However, the litigants continue to express concern that the Agencies need to address pesticides that pose the greatest threat to ESA-listed species first, as well as pressing EPA to meet their ESA obligations for new chemical registrations.~~

~~In an effort to reduce the amount of time that staff have to devote to respond to litigation,~~ ~~the~~ Agencies have worked with the litigants to align existing settlements and lawsuits so that the Agencies can focus on national-level consultations on all ESA-listed species, rather than focus on single species, or a small subset of species in smaller geographical areas that were the initial focus of the litigation. Based on recent settlement agreements as part of ongoing litigation against EPA, NMFS, and FWS (i.e., NCAP v. EPA, NCAP v. NMFS, CBD v. EPA and CBD v. FWS), the Agencies agreed to coordinate completion of nationwide consultations for nine pesticides, carbaryl, chlorpyrifos, diazinon, malathion, methomyl, glyphosate, atrazine, propazine and simazine. The dates provided for completion of consultation in those settlements are December, 2017 for chlorpyrifos, diazinon, and malathion, ~~December, 2018 for carbaryl and methomyl, and 2022 for glyphosate, atrazine, simazine and propazine.~~ Further information on ESA-related litigation and associated settlement agreements can be found at the following link: <http://www.epa.gov/endangered-species/endangered-species-litigation-and-associated-pesticide-limitations>. The Agencies are also working on out year planning for biological opinion development beyond 2022.

Commented [KR22]: In this settlement, I thought EPA agreed to a date for initiating consultation. If so, we should say what that date is.

Commented [DM23R22]: BE date for those four is 6/30/2020.

Commented [DM24]: FWS please confirm that this is correct.

Although the Agencies have been able to reach agreement with existing litigants to allow the Agencies to focus their work on implementing the NAS NRC report recommendations through the nationwide consultations identified above, EPA is now facing several new legal challenges to its approval of new active ingredients from these and other litigants. Unfortunately, these new

legal challenges will continue to divert limited resources from the Agencies' current focus on existing pesticides that potentially pose broader risk concerns for ESA-listed species and designated critical habitat than the proposed new active ingredients.

National Academy of Sciences Study Implementation

(Supports 2013 NAS NRC Report Recommendations 1-3)

Commented [KR25]: Not sure why we need this here

On March 10, 2011, the Agencies requested that the NRC convene a committee of independent experts. "The committee was asked to evaluate EPA's and the Services' methods for determining risks to ESA-listed species posed by pesticides and to answer questions concerning the identification of the best scientific data, the toxicological effects of pesticides and chemical mixtures, the approaches and assumptions used in various models, the analysis of uncertainty, and the use of geospatial data."⁴ Specifically, the committee was asked to evaluate the following:

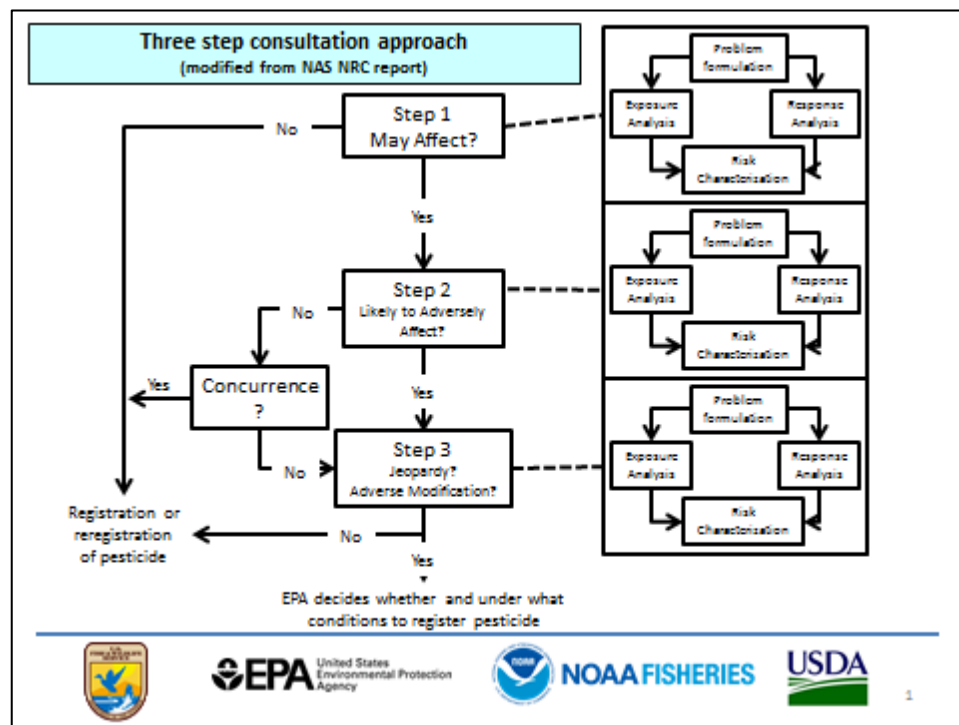
- protocols used by the Agencies to review the best available scientific methods for projecting these effects and consider options for the development of any additional methods that are likely to be helpful;
- to consider the scientific information available to assess the potential effects of mixtures and inert ingredients; to consider the selection and use of uncertainty factors to account for lack of data and how the choice of those factors affect estimates of uncertainty;
- to advise on the use of models to assist in analyzing the effects of pesticide use; and
- Evaluate the use of geospatial information and datasets in assessing the risk to ESA-listed species and designated critical habitat from pesticides.

On April 30, 2013, the NAS NRC provided their recommendations to the Agencies in the form of a report entitled: "*Assessing Risks to Endangered and Threatened Species from Pesticides*." Upon receipt of the study report, the Agencies began a joint review and discussion of the recommendations and developed a plan for their implementation. As part of the implementation plan, the Agencies determined which recommendations could be implemented immediately, which recommendations would take longer to implement, and which recommendations required additional interagency discussions. The Agencies developed and are continuing to refine the NAS NRC report interim approaches can be found at the following link:
(<http://www2.epa.gov/sites/production/files/2015-07/documents/interagency.pdf>).

⁴ Assessing Risks to Endangered and Threatened Species from Pesticides (National Research Council, 2013; http://www.nap.edu/catalog.php?record_id=18344)

NAS NRC Report Recommendation: The Three-Step Approach

The Agencies are addressing the NAS NRC report overarching recommendation to implement a three-step risk assessment and consultation approach, as displayed in the graphic below.



Step 1 - ('No Effect/May Affect' determinations) - EPA makes the "no effect/may affect" determination independently of the Services at Step 1. If EPA determines that a pesticide's registration (or as it is more commonly known: re-registration), will have "no effect" on ESA-listed species, it may move forward with or continue a pesticide's registration without consulting with the Services. If EPA determines that a pesticide's registration "may affect" ESA-listed species, the pesticide's potential impact on ESA-listed species must be considered under Step 2. The "No Effect/May Affect" determination will largely be based on the overlap of the action area with the ESA-listed species' ranges and designated critical habitats (*i.e.*, any species or critical habitat that overlaps with the action area will be considered a "May Affect"). The action area will be defined by identifying pesticide use areas (*i.e.*, the pesticide use footprint) based on currently registered labeled uses (*i.e.*, the Action). In addition, the action area will include a footprint that extends beyond the use sites to incorporate off-site transport including pesticide spray drift and runoff.

Step 2 - (“Not Likely to Adversely Affect (NLAA)/Likely to Adversely Affect (LAA)” determinations) - EPA determines whether a pesticide’s registration is “LAA”, or “NLAA” ESA-listed species. When EPA determines that an effect is “NLAA”, they must seek concurrence from the Services. When EPA determines that an effect is “LAA,” EPA and the Services enter into formal consultation, and Step 3 is initiated. To determine whether the call for an ESA-listed species and designated critical habitat is an NLAA or LAA, a weight-of-evidence approach that evaluates risk hypotheses and associated lines of evidence will be used. Exposure values will be based primarily on existing fate and transport model results that assess the range of labeled uses of the pesticide (rates, methods). Supporting documentation for existing models can be found at the following link: <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment>. A variety of tools have been implemented to assess species responses that are listed in the Major Accomplishments section later in the report.

Step 3 (“Jeopardy/No Jeopardy” and “Adverse Modification/No Adverse Modification” determinations) - For all of those species and critical habitat designations found to warrant determinations of LAA, NMFS and FWS will determine “jeopardy” or “no jeopardy” and “adverse modification” or “no adverse modification” for these resources, respectively. These determinations will be based on a weight-of-evidence approach that evaluates risk hypotheses and associated lines of evidence for each of these ESA-listed species.

Three teams of interagency scientists from the Agencies are currently working to complete effects determinations (i.e., Steps 1 and 2) for chlorpyrifos, diazinon, and malathion. All three teams have developed species sensitivity distributions for fish, aquatic invertebrates, and birds and are currently reviewing other toxicity data available in the literature. EPA has developed an analytical tool called the data array builder can be found at the following link: <http://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments#Effects>).

This tool identifies and groups data (e.g., endpoints specific to family, species and endpoints) providing a graphic representation of relevant toxicity data. The Agencies will soon begin to work on the methodology for Step 3, as we move from the development of Biological Evaluations to Biological Opinions.

Progress to Date – Joint Agency Meetings and Stakeholder Workshops (Supports 2013 NAS NRC Report Recommendation 4)

Joint Agency Meetings

In addition to the three-step approach described above, the NAS NRC report provided a number of other recommendations for the Agencies to consider. In an effort to begin implementing the recommendations on upcoming consultations, the Agencies have held four internal workshops to develop the NAS NRC report interim approaches to address the NAS NRC report recommendations. Significant progress occurred at each of these workshops, and each are

Commented [DM26]: In order to address the conference committee report language asking us to address how we’re addressing the obstacles created by the vacatur of the counterpart rule and what our plans are for updating the ACA associated with that, we should explain that the NAS report and the implementation process we’re going through will in fact help us overcome the concerns identified in the decision vacating the rule – i.e., that EPA’s and the Services’ approaches were in fact not in sync. This implementation process is designed to create the sort of agreement and consistency that the agencies failed to achieve in the development of the counterpart regs and ACA.

Commented [KR27]: Not sure why we need this here

discussed briefly below, with examples provided of some of the agreements that have been reached thus far.

August, 2013 Inter-Agency Workshop - The Agencies conducted their first technical workshop during the week of August 5, 2013, in which the NAS NRC report interim approaches for estimating risks to ESA-listed species from pesticides were developed jointly by the Agency scientists. The white paper describing the NAS NRC report interim approaches entitled, “Interagency Approach for Implementation of the National Academy of Sciences Report” (11/13/2013) is available at the following link: (<http://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf>).

As part of the NAS NRC report interim approaches, the Agencies agreed on the three-step consultation process and developed thresholds to evaluate direct and indirect effects to ESA-listed species and designated critical habitats for Steps 1 and 2. The Agencies also began to identify the need to develop approaches/methods for addressing the following items:

- A common approach to weight-of-evidence analyses, using quantitative and qualitative information for making NLAA/LAA determinations in Step 2 (and jeopardy and adverse modification critical habitat decisions in Step 3).
- A mechanism for obtaining and sharing the best available geospatial information on species’ ranges and critical habitat.
- Definitions for different types of aquatic “bins” (*i.e.*, type of water body) for aquatic species for use in Steps 2 and 3 for exposure modeling. The water body may vary by depth, width, and flow; it may be static, flowing, estuarine, intertidal, subtidal, or offshore marine.
- Guidance on the construction and use of species sensitivity distributions.
- An agreed upon dataset and method to define agricultural pesticide use areas by aggregation of crop categories in the NASS CDL produced by USDA.

May, 2014 Inter-Agency Workshop - The Agencies conducted their second technical workshop during the week of May 5, 2014 to continue developing and refining the NAS NRC report interim approaches for assessing risks to ESA-listed species from pesticides. In addition, the Agencies developed a draft annotated outline for the Biological Evaluation, which includes Steps 1 and 2. This draft outline formed the basis of the first three nationwide Biological Evaluations to be completed for the three pilot chemicals (chlorpyrifos, diazinon, and malathion).

November, 2014 Inter-Agency Workshop - The Agencies conducted their third internal workshop during the week of November 17, 2014, with the overall goal of fostering an understanding of how to make and support effect determinations for ESA-listed species and designated critical habitat in the draft Biological Evaluations for the three pilot chemicals. These efforts involved highly detailed technical discussions regarding exposure modeling to derive estimated pesticide concentrations in different aquatic waterbodies or “bins” and a preliminary weight-of-evidence approach.

The weight-of-evidence approach constructs lines-of-evidence from effects data and applies scientific validity and relevance criteria in weighing and aggregating lines of evidence to connect exposures to effects. The Step 2 analysis ultimately informs the Step 3 Biological Opinion where overall effects to populations and species are determined. Progress towards implementing the NAS NRC report recommendations included a series of agreements on the best available science to be applied to the first three pilot chemicals, with the recognition that the Biological Evaluations will be published in draft form for public comment and with the intention to learn from these pilot cases and modify as needed in the future.

Additional progress in implementing the NRC NAS report recommendations made at this workshop include, but are not limited to:

- Approaches to identify data sources and strategies for mapping non-agricultural pesticide uses, methods to consider offsite transport of pesticides via downstream effects and spray drift into the action area, and efforts to obtain refined ESA-listed species location data.
- Potential methods for identifying and reviewing additional open literature data including a discussion of data relevance and data quality.
- Potential methods to qualitatively evaluate the pesticide mixtures.
- A decision framework to ensure that the best available data are used to assemble lines of evidence in the weight-of-evidence approach including a strategy to consider the likelihood of potential effects where quantitative data are available, and criteria to determine the level of confidence (weight) to give to each line of evidence a ranking as low, moderate or high.
- Agreement on information required in the Biological Evaluations to support development of the Biological Opinions.

January, 2016 Inter-Agency Workshop - The Agencies conducted their fourth internal workshop during the week of January 25, 2016, with the overall goal of fostering an understanding of how to make and support effect determinations for ESA-listed species and designated critical habitat in the draft Biological Opinions for the three pilot chemicals. The Agencies discussed a number of items that can influence Step 3:

- What is the Action Area – in relation to a species range, and considering drift and run-off, how much of the action area over-laps with a species range. Within the species range, what the life history stages are associated with this overlap? Is there a seasonality component to these life-history stages?
- Pesticide usage and ESA-listed species/designated critical habitat - What can we say about the timing of pesticide uses (if specified on the labels) relative to the presence of ESA-listed species/designated critical habitat?
- Species Life Stage - Considering each of the lines of evidence that were analyzed in the Biological Evaluations, what are the anticipated magnitudes of effects and anticipated responses for each species and or their life stages present in the aquatic bins? What additional life stage information needs to be considered? (e.g. years to reach reproductive age, fecundity)? What are the behavioral (social) aspects of the species

(e.g., solitary, schooling)? What do we know about the overall number of individuals in the population - in total, and by life stage?

- Habitat - Can the species broaden its range, or are there baseline habitat issues that may be limiting their ability to viably do so? What are these issues and how may the action affect these?
- Other information - What are the other aspects of the species status that may be informative (e.g., population declining, stable, or increasing)?

~~Post-Subsequent to this workshop~~ these workshops, the Agencies are now working to develop Step 3 interim measures that will be used to develop the draft Biological Opinions for the three pilot chemicals.

Public Participation and Transparency (Supports 2013 NAS NRC Report Recommendation 4)

Existing processes for registration, registration review, and consultation provide multiple opportunities for stakeholder engagement. Although federal law only requires limited public participation in the pesticide registration process, EPA's Pesticide Program began implementing a public participation process for certain registration actions in October, 2009. The public participation process for registration actions provides a meaningful opportunity for the public to comment on major registration decisions at a point in the registration process when comprehensive information and analysis are available. EPA currently uses the outlined public participation process for the following types of applications:

- new active ingredients;
- first food use;
- first outdoor use;
- first residential use; and
- other actions of significant interest.

The current post-registration review process -known as registration review - was created by section 3(g) of FIFRA and mandates that EPA review pesticides not less often than every 15 years. Under section 3(g)(1)(A)(ii), EPA has established procedures for registration review in its final rule published in the Federal Register (71 FR 45,732, Aug. 9, 2006, as amended at 73 FR 75595, Dec. 12, 2008) and codified at 40 CFR Part 155 Subpart C -Registration Review Procedures. Under the procedures established per 40 CFR part 155 Subpart C, three specific time points have been identified for public notification and comment during registration review:

- initiation of a pesticide's reevaluation;
- when a draft risk assessment has been conducted; and
- for a proposed registration review decision.

Commented [KR28]: Shouldn't we discuss the 2013 paper on increasing transparency in the process?

Commented [KR29]: Same comment as before

In addition to the public review and comment periods outlined above, EPA may meet with stakeholders at any time during registration review, either through Agency initiation, or stakeholder request, to discuss an ongoing registration review (40 CFR Part 155.52).

EPA's Endangered Species Protection Program (ESPP) is the EPA program for addressing the requirements of the ESA in connection with EPA's implementation of FIFRA. [Announced in a November 2, 2005, Federal Register Notice, the 2005 ESPP document 10⁵ outlines three opportunities for public input and participation during registration review:

- prior to a "may affect" determination by EPA;
- when identifying potential mitigation if a risk assessment identifies a listed species concern; and
- prior to issuance of a Biological Opinion to EPA by NMFS and FWS.

Under the ESPP, EPA will generally engage the public in each of these three stages of its ESA-related work. The first and second opportunity for public review and comment meld with existing procedures established for registration review. These existing opportunities for public input have been strengthened and enhanced through process improvements jointly developed by the Agencies as described below.

In addition to the stakeholder workshops described below EPA also uses the web application "Bulletins Live Two," to set forth geographically specific pesticide use limitations for the protection of threatened and endangered species and their designated critical habitat. "Bulletins Live Two" can be found at the following link: <http://www.epa.gov/endangered-species/endangered-species-protection-bulletins>.

"Bulletins Live Two" is geo-coded making it possible for users to zoom in and out and focus on their area of interest, conduct searches for products (by name and EPA registration number) in addition to active ingredients, and download printable Bulletins. These upgrades, implemented in 2015, included:

- an interactive map;
- different base maps (satellite, street, geographic, etc.) to help users determine if their application area is in a pesticide use limitation area;
- advanced searches for active ingredient, product (by name or registration number), location (state, county, specific address); and
- an enhanced system to receive public comments on draft Bulletins.

These upgrades allow the web application setting forth species protections to be more easily accessible and understandable for users likely to be affected by species protections.

Commented [KR30]: I don't think citing the 2005 notice is appropriate. That notice was superseded by the transparency paper issued in 2013. See: <https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0442-0038>.

Commented [DM31R30]: Well, not entirely superseded since that document goes beyond talking about reg review process. But as to the interface between registration review and ESA, yes, so I agree it makes sense to really just discuss the transparency paper here.

⁵ <http://www.gpo.gov/fdsys/pkg/FR-2005-11-02/pdf/05-21838.pdf>

Stakeholder Workshops

The Agencies' efforts to improve transparency for pesticide consultations began as early as 2011 with the Minor Crop Farmer Alliance workshop, held in Denver, Colorado in May, 2011, which addressed grower/user concerns. There was general agreement that information was needed to clarify and confirm product labeling information, identify where crops are grown, and that growers need to be engaged early and often. The meeting minutes and materials provided for and discussed at the workshop can be found at the following link: <http://www.ffva.com/imispublic/Content/NavigationMenu2/AgResources/Aglinks/Meetingmaterials/default.htm>. Copies of the individual presentations can be found on the following links: Florida Fruit & Vegetable Association (www.ffva.com) and the California Citrus Quality Council (<http://calcitrusquality.org/>).

In response to the stakeholder feedback gained in 2011, the Agencies prepared and proposed for public comment the paper entitled, "Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives" (hereafter referred to as the Stakeholder Paper). The Agencies finalized the Stakeholder Paper in March, 2013. The paper can be found the following link: www.regulations.gov, in the following docket: EPA-HQ-OPP-2012-0442. The processes described in the Stakeholder Paper supersede similar provisions in the 2005 ESPP document.

Since the release of the NAS NRC report in 2013, the Agencies have held a number of stakeholder workshops. A brief chronological summary of these stakeholder workshops and associated accomplishments are provided below:

November, 2013 Stakeholder Workshop - The NAS NRC report interim approaches developed at the Agencies' technical workshop in August, 2014 were presented to the public during a stakeholder's workshop on November 15, 2013. Presentation materials from the stakeholder workshop are available at the following link: <http://www2.epa.gov/sites/production/files/2015-09/documents/nas-rollout.pdf>. At this workshop, the Agencies communicated that the NAS NRC report interim approaches will be incorporated into the risk assessment process on a "day forward approach." This means that our shared scientific approaches, once fully developed and vetted, will be applied to pesticide reviews from that point in time and going forward rather than reworking assessments and decisions already completed.

April, 2014 Stakeholder Workshop - On April 22, 2014, at the request of stakeholders, the Agencies held a public workshop to provide a forum for stakeholders to present scientific and technical feedback on the NAS NRC report interim approaches. Representatives from the pesticide industry and non-governmental organizations attended the workshop and provided feedback. Members of the original NAS NRC panel, Defenders of Wildlife and industry stakeholders presented approaches and methods for refining Steps 1 and 2 of the three-step consultation process, evaluating geospatial information on species and crop location, using species biological information and critical habitat attributes, and integrating weight-of-evidence and uncertainty analysis as part of the risk assessment process. The scientific and technical

Commented [DM32]: Given the need to also update the section 1010 study and report in this report to Congress, I would think we would want build on these statements by bringing in our GIS mapping efforts and the bulletins live approach in order to show (and take credit in this report) that we are continuing with our efforts to develop approaches that will ensure species' protection while minimizing impacts on the producers of food and fiber commodities. In order to address at least to some extent one of the other requirements of the report that is only minimally addressed in this draft, you could also note somewhere in this section that obtaining and understanding use and usage information from registrants and growers through the registration review process will also help to ensure that RPAs are economically and technologically feasible.

Commented [KR33]: So given this, why cite the 2005 document?

presentations are available in the public docket (EPA-HQ-OPP-2014-0233) which can be found at the following link: <http://www.regulations.gov/>.

October, 2014 Stakeholder Workshop - The third stakeholder workshop, held on October 6, 2014, included presentations from FWS on the effort to obtain listed species range maps and from EPA on the status of the Agencies' work on the three pilot chemicals to further develop and implement the NAS NRC report interim approaches. There was significant stakeholder interest in potential changes to current methods for modeling aquatic exposure, refinements to reduce the number of species for which consultation is required, and the timeline for completion of the draft Biological Evaluations and associated decisions relative to modeling, use of probabilistic methods, and the weight-of-evidence analysis. External stakeholders, mainly pesticide industry representatives, presented on the role of multiple species and crop attributes in understanding the potential for exposure, characterization of uncertainty in aquatic risk assessments, probabilistic methods, and weight-of-evidence analysis.

As part of the FWS presentation on the effort to obtain geospatial data for ESA-listed species for use in pesticide Biological Evaluations and Biological Opinions, FWS reported plans to request sub-county level ESA-listed species range data from species experts within their Field Offices based on review of map kits prepared by the Federal Endangered Species Task Force (FESTF). This effort was proposed to occur in three phases with Phase One to include all species except for mammals and plants, Phase Two to include the remainder of species in lower 48 contiguous states, and Phase Three to include range maps for plants and other species occurring only on the Pacific Islands.

Commented [C34]: FWS needs to review this. Can we talk more about the species range data and add in a map?

April, 2015 Stakeholder Workshop - A fourth stakeholder meeting held on April 15, 2015, reviewed the Problem Formulation Framework, including the description of the Federal action, mapping pesticide use patterns, species ranges, and the risk hypothesis and weight-of-evidence approach. More information about this meeting, including the agencies' presentations can be found at the following link: <http://www.epa.gov/endangered-species/assessing-risks-endangered-and-threatened-species-pesticides-4th-interagency>.

Summer, 2016 Proposed Stakeholder Workshop – Two conference calls were held with stakeholders who participated in previous workshops on November 30, 2015, to identify agenda topics and solicit ideas for a meeting format that allows for increased participation and interaction between stakeholders and agency technical staff. Based on feedback from these conference calls, the Agencies, in conjunction with a steering committee composed of representatives from the Agencies, industry, and non-governmental organizations, are conducting a 2-day stakeholder workshop.

Major Accomplishments

The following accomplishments illustrate the important progress to date that has resulted from the long-lasting and collaborative relationship on the ESA consultation process among the Agencies with the assistance of the USDA. In modifying the traditional ESA consultation process for Biological Opinion development to allow for interagency review, comment and participation in the process, we have been able to combine the expertise of the Agencies, and in

doing so, improve develop what we believe to be scientifically credible, legally defensible Biological Evaluations and Biological Opinions.

Joint Agency Technical Accomplishments

(Supports 2013 NAS NRC Report Recommendation 1-3)

A significant effort has been made to align, where appropriate and applicable, the technical analyses of the Agencies as we develop the Biological Evaluations and Biological Opinions for this work. Progress to date includes:

- Agreement on geospatial data to define pesticide use areas for agricultural and non-agricultural use patterns
- A refined set of shared ESA-listed species range maps based on collaborative work with FESTE
- A common weight-of-evidence method including agreement on the risk hypothesis, lines of evidence, criteria to evaluate and assign weight or confidence to each line of evidence, and a method to integrate the results to draw supporting conclusions for Step 2 (NLAA/LAA determination)
- Guidance on the construction and use of species sensitivity distributions to derive acute toxicity thresholds. The SSD toolbox can be found at the following link:
<https://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments>
- Methods for qualitative analysis of mixtures, inert ingredients, and surfactants
- Agreement on aquatic habitat bins which include static, flowing, and estuarine/marine habitats and methods for predicting regionally-specific aquatic exposure concentrations for each bin based on existing EPA models
- Assignment of all aquatic ESA-listed species including different life stages (*i.e.*, juvenile vs. adult) to the appropriate aquatic bins. The assignments may change after comments are reviewed post the public comment period for the Biological Evaluations
- Agreement on the review of all registrant-submitted and open literature data for the three pilot chemicals including associated thresholds for each line of evidence and taxonomic group and associated data arrays
- Compilation and agreement on life history data (*e.g.*, diet, body weight, habitat, etc.) for all ESA-listed species including identification of model input parameters based on this information

- Tool development to advance and automate the estimation of pesticide exposures and effects for ESA-listed species for EPA's nationwide assessments, resulting in the following:
 - Automation of thousands of aquatic modeling runs and aid in the post-processing of these results. These tools will automatically generate graphs and tables including probability distributions of exposure over time to help characterize the duration and magnitude of exposure.
 - Integration of existing terrestrial modeling tools (T-REX, T-HERPS, TerrPlant, AgDRIFT, Bee-REX) to make effects determinations for ESA-listed mammals, birds, reptiles, amphibians, terrestrial plants, and invertebrates in one model (TED – Terrestrial Effects Determination tool).
 - Implementation of probabilistic models including TIM and McNEST that assess pesticide risks to birds.
 - Tools that better portray all of the toxicity effects data including the data array builder.
- Development of new tools and aggregated models intended to analyze and visualize the estimated exposures and available effects data in an automated fashion. Provisional models released as part of the December 2015 draft Biological Evaluation sections can be found at the following link: <http://www.epa.gov/endangered-species/provisional-models-endangered-species-pesticide-assessments>.

Published Presentations and Papers

(Supports 2013 NAS NRC Report Recommendation 4)

In addition to developing scientifically credible and legally defensible technical analyses, the Agencies have also presented their work in a number of scientific and stakeholder forums to receive feedback and provide updates on scientific methods developed by the Agencies to assess pesticide risks to ESA-listed species. Appendix 1 lists presentations presented to support agency technical work on pesticides. Agency staff also published a number of peer reviewed research publications related to this work:

- Macneale, K.H., Spromberg, J.A., Baldwin, D.H., and Scholz, N.L. 2014. "A modeled comparison of direct and food web-mediated impacts of common pesticides on Pacific salmon." *Public Library of Science ONE*, 9:e92436.
- Laetz, C.A., Baldwin, D.H., Hebert, V., Stark, J.D., and Scholz, N.L. 2014. "Elevated temperatures increase the toxicity of pesticide mixtures to juvenile coho salmon." *Aquatic Toxicology*, 146:38-44.
- Laetz, C.A., Baldwin, D.H., Hebert, V., Stark, J.D., and Scholz, N.L. 2013. "The interactive neurobehavioral toxicity of diazinon, malathion, and ethoprop to juvenile coho salmon." *Environmental Science & Technology*, 47:2925-2931.

- Laetz, C.A., Hecht, S.A., Incardona, J.P., Collier, T.K., and Scholz, N.L. 2015. Ecological risk of mixtures. In: Aquatic ecotoxicology: advancing tools for dealing with emerging risks. C. Amiard-Triquet, J.-C. Amiard, and C. Mouneyrac (eds). Academic Press, pp. 441-462.
- Brander, S., Hecht, S., Kuivila, K. The Challenge: "Bridging the gap" with fish: Advances in assessing exposure and effects across biological scales. 2015. Environmental Toxicology and Chemistry Globe Series.

Successfully Completed Consultations

The Agencies ~~successfully~~ ~~successful~~ completed pesticide consultations for several pesticide actions which are discussed in further detail below. Common factors leading to successful pesticide consultations include early engagement between the Agencies and affected stakeholders, mitigation measures which consider existing best management practices, and open dialog between those stakeholders during the consultation process.

- Rozol - Rozol™ is an anticoagulant rodenticide used to control black-tailed prairie dogs. The consultation was the result of a lawsuit, in which the court-ordered EPA to cancel the Rozol's™ registration. EPA and FWS worked collaboratively with stakeholders (registrants) very early during the consultation to identify conservation measures that protect species and their critical habitat. Early mitigation termed "conservation measures" was agreed to prior to the final biological opinion. Incorporation of conservation measures protecting species and their designated critical habitat resulted in a "no jeopardy" conclusion, making RPAs unnecessary. Technologically and economically feasible RPMs were developed collaboratively among FWS, EPA, and the registrant. The consultation was completed efficiently and species protections put in place quickly.
- Kaput - Kaput™ is another anticoagulant rodenticide used to control black-tailed prairie dogs. It is similar to Rozol™, but contains a different active ingredient. Kaput™ was not yet registered; however, the Agencies built upon their success from the Rozol™ consultation and applied the same early stakeholder engagement strategy to implement risk mitigation measures that would support a "no jeopardy" conclusion, thus negating the need for RPAs, and achieving species protections through negotiated RPMs. A Biological Opinion was completed for Kaput™ prior to registration of the product. The measures outlined in the Biological Opinion were then made conditions of registration for the product. As a result, the product, Kaput™, came on the market with these species protections already in place.
- Biological Opinion for thiobencarb implemented - Recent successes illustrate necessary and appropriate RPMs can be achieved through early collaboration and stakeholder engagement. Thiobencarb is one of the pesticides included in the lawsuit related to pesticide impacts on Pacific Northwest salmonids. Early engagement between NMFS, EPA, the California Department of Pesticide Regulation, the registrant, and the California

Rice Commission allowed EPA and NMFS to develop an implementation plan for thiobencarb use on rice in California. NMFS considered and used existing state programs to mitigate risks to species and protect designated critical habitat. This resulted in a “no jeopardy” conclusion.

- Biological Opinion for diflubenzuron, propargite, and fenbutatin-oxide completed - Diflubenzuron, propargite, and fenbutatin-oxide are three of the pesticides included in the lawsuit related to pesticide impacts on Pacific Northwest salmonids. NMFS completed the Biological Opinion on December 24, 2014. EPA and NMFS worked with the registrants to identify pesticide uses that posed the greatest risks to salmonids. Registrants proposed several label modifications to labels to reduce risk to the species that were incorporated into the Biological Opinion’s effects analysis. Because this was a “jeopardy” conclusion, EPA is working on developing alternative RPAs to present back to NMFS to implement the Biological Opinion.

Re-Registration Review

In addition to the successful pesticide consultations described above, EPA has effectively been able to implement mitigation measures intended to protect ESA-listed species and designated critical habitat as part of stakeholder engagement prior to consultation during its registration review program.

- Starlicide - Starlicide™ (renamed DRC-1339) is an avicide used mainly in feedlots, as well as staging areas in rice growing areas. Typically, Starlicide is used in the form of treated baits and is currently undergoing registration review. Although consultation has not been initiated, it provides an example of positive outcomes from early stakeholder engagement prior to consultation. In the interest of reducing non-target exposure, EPA met regularly with USDA's Animal and Plant Health Inspection Service (APHIS) and the U.S. Rice Federation to discuss ways to minimize exposure and reduce costly data requirements. The U.S. Rice Federation suggested tilling the soil after the application/bait period to bury leftover bait, making it less accessible to non-target species. This would be a practical mitigation measure that is technologically and economically feasible for the rice use, and may work for some of the other broadcast uses as well. The goal of these outreach efforts is to eliminate or limit the potential for non-target exposures from the rice use and other broadcast uses, subsequently negating the need for the majority of the data requirements for Starlicide™. This modification will be reflected in the consultation EPA initiates with FWS as it works to complete registration review. The Agencies are working towards this kind of successful outcome through collaborative dialogue with stakeholders resulting in technologically and economically feasible mitigation measures, which when implemented have the dual benefits of precluding the need for expensive data requirements, and reducing, or eliminating concerns for ESA-listed species.
- Gas cartridges - Gas cartridge products are used to control burrowing mammals and are available in small and large sizes. These products are currently undergoing registration

review, and informal consultation with FWS has been initiated. The registration review interim decision on gas cartridges provides an example of achieving risk mitigation for some listed species through informal consultation. EPA and APHIS, one of the registrants for some of the gas cartridge products worked closely together to develop risk mitigation measures that build upon work already completed under previous consultations with FWS. APHIS and the other gas cartridge registrants have agreed to place the risk mitigation measures on their product labels narrowing the scope of consultation. Based on EPA's September, 2015, interim decisions on the gas cartridges, Bulletins are being developed to restrict gas cartridge product use in the range of four listed species including the gopher tortoise, Hualapai Mexican vole, Mount Graham red squirrel, and the Utah prairie dog.

- Silica - Silica (Diatomaceous Earth) is an insecticide that is currently undergoing registration review. EPA and FWS successfully completed informal consultation on 57 listed species that may be directly or indirectly affected by the use of silica. FWS concurred with EPA's determination that silica "May affect, but is not likely to adversely affect" these species.

All of the examples described above reflect the benefit of working closely with stakeholders prior to initiation of consultation and sharing the conclusions of past consultations, allowing the Agencies to build upon work done for existing consultations. These positive outcomes underscore the importance of early engagement with stakeholders, consideration of existing consultations, state programs and state co-regulators, and flexibility.

ESA-listed Species Mitigation Measures for Pesticides Actions

At the November, 2014 interagency workshop, the Agencies reached agreement on the process by which EPA will, in appropriate circumstances, seek to proactively get ESA-listed species mitigations in place early in the registration review process. Mitigation focus is on avoidance and minimization through label changes at Steps 1 and 2, with these implemented as changes to the proposed action. EPA will work with the registrant to get label clarifications and understand use patterns. Timing of agreement on label changes will depend on interactions with the registrant(s). The Agencies will also discuss experience with compensatory mitigation, considerations for doing it well, and the key issues it would raise in the context of pesticide re-registrations and, then, possibly follow up with stakeholders interested in exploring this option. For those registrations when the registrant(s) is/are willing to make voluntary changes to the label, EPA will send a package of information to the NMFS AND FWS between the draft Biological Evaluation (preliminary risk assessment) and the final. This will be sent as a change to the federal action. The package will include a transmittal letter from the Director of EPA's Pesticide Re-evaluation Division summarizing the negotiations with the registrant to obtain label changes, a table capturing the label changes, and the commitment letters from the registrants with the anticipated dates for those changes.

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Commented [DM37R36]: Do we really want to be this specific about the process such that we effectively lock ourselves in to one approach for early mitigation? I would think we'd want to stop short of including the highlighted text and leave ourselves flexibility for how we might choose to go about getting early mitigation.

ANTICIPATING, MINIMIZING, AND RESOLVING DELAYS

Creating efficiencies in how the Agencies develop the Biological Evaluations and Biological Opinions is critical to developing a long-term and sustainable process. The Agencies are ~~talking~~ taking the following actions toward this end:

- Biological Evaluation review - The first round of draft Biological Evaluation sections and provisional models for the three pilot chemicals, chlorpyrifos, diazinon, and malathion, were released for public review in December, 2015. The completed draft Biological Evaluations were released for ~~aan-extended~~ 60-day public comment in April, 2016. The point here is to ensure transparency and get feedback from the public to build into the document development process as early as possible.
- Stakeholder workshop – In order examine Steps 1 and 2 and propose efficiencies in these steps, the Agencies, in conjunction with a steering committee composed of representatives from the Agencies, industry, and non-governmental organizations, are conducting a 2-day stakeholder workshop. This workshop will be held in the summer of 2016.
- Review of existing pesticide Biological Opinions - EPA compiled information on existing Biological Opinions for the approved use of pesticides on federal lands managed by, for example the US Forest Service and the Bureau of Land Management. By building on existing consultations that have already been completed for certain pesticides, EPA believes that efficiencies can be introduced into the nationwide pesticide consultations that will occur during registration review. RPAs and RPMs identified in previous Biological Opinions can serve as the foundation for label clarifications and early risk mitigation since previous consultations have identified such measures as being helpful to ESA-listed species. This information will be used to see where the Agencies can leverage existing consultation information to reduce duplication of effort and save resources.

Conclusion

The scientific procedures and methodologies developed as part of the NAS NRC report interim approaches are the most comprehensive developed to date for ESA-listed species pesticide consultations. In response, the Agencies developed a joint, highly robust process to implement the consultation process. The Agencies will continue to implement the NAS NRC study's recommendations to strengthen the foundation of our work together.

We continue to collaborate with key stakeholders to implement the NAS NRC report interim approaches to national-level risk assessments for pesticides and coordinate our responses on litigation. In keeping with this, the Agencies are committed to continue a robust dialogue with all

of our stakeholders to ensure transparency throughout the pesticide consultation process and fully consider effects to and from agriculture. The Agencies are committed to producing risk assessments, Biological Evaluations and eventually Biological Opinions that are scientifically credible, legally defensible, and take into account the concerns and advice voiced by those stakeholders and produce tangible, implementable that support species conservation.

Appendix 1: Presentations Given to Support Agency Technical Work on Pesticides

Title	Authors	Meeting
ESA Draft Biological Evaluations and Path Forward	Anita Pease	CropLife America (CLA) and RISE (Responsible Industry for a Sound Environment) Spring Conference, 2016
NEED TITLE	Kris Garber	CropLife America (CLA) and RISE (Responsible Industry for a Sound Environment) Spring Conference, 2016
Step 3: An Evolving Approach to Endangered Species Act Pesticide Consultations	Cathy Tortorici	CropLife America (CLA) and RISE (Responsible Industry for a Sound Environment) Spring Conference, 2016
Weight-of-Evidence: An evolving approach to ESA pesticide consultations	Cathy Tortorici	CropLife America (CLA) and RISE (Responsible Industry for a Sound Environment) Spring Conference, 2016
Use of toxicological data in the assessment of pesticide risk to threatened and endangered species	George Noguchi, U.S. Fish and Wildlife Service/ Ecological Services; Sara Pollack, U.S. Fish and Wildlife Service / Ecological Services; Melissa Panger, U. S. EPA / Office of Pesticide Programs; David Baldwin, NOAA Fisheries / Northwest Fisheries Science Center; Pat Shaw-Allen, NOAA National Marine Fisheries Service / Office of Protected Resources Endangered Species Division	Society of Environmental Toxicology and Chemistry (SETAC 2015) North America 36 th Annual Meeting.

Use of species sensitivities distributions and species grouping strategies in national-level endangered species risk assessments	Amy Blankinship, U.S. Environmental Protection Agency; Kristina Garber, Office of Pesticide Programs Environmental Fate and Effects Division; Matthew Etterson, U.S EPA / ORD/NHEERL/Mid Continent Ecology Division; Cathy Laetz, NOAA / Northwest Fisheries Science Center; Sara Pollack, U.S. Fish and Wildlife Service / Ecological Services; Pat Shaw-Allen, NOAA National Marine Fisheries Service / Office of Protected Resources Endangered Species Division	SETAC 2015
A Weight-of-Evidence Approach for Making Effects Determinations for Federally Listed Species and Pesticides	Nancy Golden, U.S. Fish & Wildlife Service / Ecological Services; Melissa Panger, U. S. EPA / Office of Pesticide Programs; Scott Hecht, NOAA / National Marine Fisheries Service	SETAC 2015
Aquatic Modeling to Estimate Pesticide Exposure to Threatened and Endangered Species	Mark Corbin, Chuck Peck, U.S. Environmental Protection Agency; Tony Hawkes, National Marine Fisheries Service; George Noguchi, US Fish and Wildlife Service	SETAC 2015
Inclusion of multiple stressors in determinations of pesticide risk to threatened and endangered species	Cathy Laetz, NOAA / Northwest Fisheries Science Center; David Baldwin, NOAA Fisheries / Northwest Fisheries Science Center; Melissa Panger, US EPA; Karen Myers, US FWS	SETAC 2015
Assessment of risks of diazinon to the Kirtland's warbler	Kristina Garber, Office of Pesticide Programs Environmental Fate and Effects Division; Nancy Golden, U.S. Fish & Wildlife Service / Ecological Services	SETAC 2015

Reducing pesticide exposure to threatened and endangered species	Scott Hecht (NOAA), Richard Marovich, (California Department of Pesticide Regulation), Kieth Paul (USFWS), Chuck Peck (USEPA)	SETAC 2015
Development of new tools to advance the estimation of pesticide exposure and effects for listed aquatic and terrestrial species.	Chuck Peck, Colleen Rossmeisl, Kristina Garber, Matt Etterson (USEPA)	American Chemical Society (ACS 2015) 250 th National Meeting. August , 2015
Selection and use of data in the assessment of pesticide risk to threatened and endangered species.	Nancy Golden (USFWS), Pat Shaw-Allen (NOAA), Kristina Garber (USEPA)	ACS 2015
Endangered Species Act Section (7) consultation in federal land management agencies	Shawna Bautista (USFS), William P. Eckel (USEPA), Thom Hooper (NOAA)	ACS 2015
Development of generic aquatic habitats for estimating pesticide exposure in threatened and endangered species	Tony Hawkes (NOAA), Karen Myers (USFWS), Chuck Peck (USEPA)	ACS 2015
Aquatic modeling to estimate pesticide exposure to threatened and endangered species.	William P. Eckel (USEPA), Chuck Peck (USEPA), Cathy Laetz (NOAA), George Noguchi (USFWS)	ACS 2015
The use of PUR data in a national-scale assessment: Interim measures for assessing the risk of pesticides to threatened and endangered species	Tony Hawkes (NOAA), Chuck Peck (USEPA)	Annual Meeting of the California Pesticide Use Report Analysis Workgroup June, 2015

Applying an ecological risk assessment framework to national pesticide consultations: ESA definitions and practices	Scott Hecht, NOAA, Karen Myers, USFWS; Thom Hooper, NOAA; Patrice Ashfield, USFWS	Society of Environmental Toxicology (SETAC 2014) North America 35 th Annual Meeting. November, 2014.
Process for Determining Data Quality and Data Relevance for Pesticide Risk Assessments Conducted for Federally Listed Species	Melissa Panger (USEPA)	SETAC 2014
Using geospatial data to determine pesticide use areas for assessing the risk of national pesticide registrations to threatened and endangered species	Elizabeth Donovan(USEPA) , Jennifer Connolly (USEPA), Steve Lennartz(USEPA), James Cowles (USEPA); Keith Paul (USFWS); Thom Hooper (NOAA)	SETAC 2014
Using Generic Aquatic Habitats to Estimate Pesticide Exposure to Threatened and Endangered Species	Tony Hawkes (NOAA), Mark Corbin (USEPA), Drew Crane (USFWS), Karen Myers (USFWS), and Chuck Peck (USEPA)	SETAC 2014
Deriving protection thresholds for threatened and endangered species potentially exposed to pesticides	Matthew Etterson (USEPA), Kristina Garber (USEPA)	SETAC 2014

Weighing lines of evidence to assess pesticide risk to threatened and endangered species	Scott Hecht(NOAA), Kristina Garber (USEPA), Nancy Golden, USFWS), Wade Lehmann (USEPA), David Baldwin (NOAA)	SETAC 2014
Considerations for evaluating endangered species: A regulatory perspective	Scott Hecht (NOAA), Julann Spromberg (NOAA)	ACS 13th IUPAC International Congress of Pesticide Chemistry meeting August, 2014

From: Pease, Anita
To: gina_shultz@fws.gov; [Patrice Ashfield \(patrice_ashfield@fws.gov\)](mailto:Patrice.Ashfield@fws.gov); cathy.tortorici@noaa.gov; [Kunickis, Sheryl - OSEC](#); [Echeverria, Marietta](#); [Dumas, Richard](#)
Subject: EPA comments on Step 3 methods from FWS
Date: Friday, February 24, 2017 9:52:44 AM
Attachments: [2017_0214_Integration and Synthesis Framework EPA comments.docx](#)
[20170215_Draft I&S Summary karner bb rev wd EPA comments.docx](#)
[20170215_draft Scorecard Main MoapaDace rev wd EPA comments.docx](#)
[Draft Interpretation of Mag Tool output for Karner Blue Butterfly_02_08_17 EPA comments.docx](#)
[Plants Effects Framework 1-31-2017 EPA comments.docx](#)
[Terrestrial effects framework 1-31-2017 EPA comments.docx](#)

Hi folks,

This is the first of 2 emails transmitting EPA comment's on the Services' Step 3 methods and examples.

Attached are EPA's comments on FWS' methods including the following:

- Overarching I/S Framework
- Plant Effects Framework
- Terrestrial Effects Framework
- Scorecard and Magtool Output Interpretation for the Karner Blue Butterfly
- Scorecard for the Dace

The next email will transmit our comments on NMFS' methods and examples.

We'll look forward to seeing a revised agenda on Monday for the 2/28 meeting to discuss our comments. Thanks.

Anita Pease
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Integration and Synthesis Framework - DRAFT

This document describes the overall framework for the Integration and Synthesis section of the pilot pesticides consultation. The framework provides additional detail for the process to be used in the national pesticide consultations as more broadly described in both the Endangered Species Act and the 1998 Endangered Species Consultation Handbook.

Commented [PA1]: And based on the recommendations from the 2013 NAS report?

Background:

In accordance with policy and regulation, the jeopardy analysis in each Opinion relies on four components: (1) the Status of the Species, which evaluates the species range-wide condition, the factors responsible for that condition, and its survival and recovery needs; (2) the Environmental Baseline, which evaluates the condition of the species in the action area, the factors responsible for that condition, and the relationship of the action area to the survival and recovery of the species; (3) the Effects of the Action, which determines the direct and indirect impacts of the proposed Federal action and the effects of any interrelated or interdependent activities on the species; and (4) Cumulative Effects, which evaluates the effects of future, non-Federal activities in the action area on the species.

Commented [GK2]: And critical habitat

In accordance with policy and regulation, the jeopardy determination is made by evaluating the effects of the proposed Federal action in the context of the species' current status, taking into account any cumulative effects, as described above, to determine if implementation of the proposed action is likely to cause an appreciable reduction in the likelihood of both the survival and recovery of the species in the wild. The jeopardy analysis in the Opinion emphasizes consideration of the range-wide survival and recovery needs of the species and the role of the action area in the survival and recovery of the species. It is within this context that we evaluate the significance of the effects of the proposed Federal action, taken together with cumulative effects, for purposes of making the jeopardy determination.

Commented [PA3]: This may be an ESA "term of art", but can we clarify that this means an appreciable reduction in the survival or recovery of the population?

Due to the nature of the national pesticide consultations, which address complex analyses for >1,800 listed, proposed, or candidate species over a relatively short-time frame, much of the background information related to components 1, 2, and 4, above is considered at a coarse scale. We have endeavored to balance the need to streamline the analyses with consideration of sufficient information to arrive at our final analyses format and adequately support our conclusions.

Integration and Synthesis Process:

Each species will be addressed either singly (animals) or in habitat groupings (plants) using the approach generally described above in the Background section. Due to the large number of species considered in this Opinion, an abridged format will be used for each species or habitat grouping. This abridged format is referred to as an Integration and Synthesis (I&S) Summary Scorecard (or “Scorecard”). The I&S section in the biological opinion will be brief, and will present a few Scorecards as examples accompanied by an in-depth explanation of each Scorecard section and description of the analysis used. The Scorecards for each of the species and species groupings as described above will be provided in an Appendix to the I&S section of the Opinions.

Overview of Scorecards Format

The Scorecards are intended to be a brief summary of the information provided in the Opinion and its appendices, with no new information¹ generated for the analyses. The Scorecards are divided into three primary sections: 1) Species Status, Environmental Baseline, and Cumulative Effects; 2) Summary of the Effects of the Action; and 3) Rationale for the Conclusion. These sections are further defined below:

1. Species Status, Environmental Baseline, and Cumulative Effects Summary

a) Species Status

For animals, this information consists of selected fields from the Status of the Species related to species and population information, threats and stressors, and life history characteristics. We reviewed information for the species as available: Status of the Species sections, EPA’s biological information for their Biological Evaluations, and other Service documents available on ECOS (e.g., recovery plans, 5-Year reviews, listing documents). For animals, we considered this information and selected broad vulnerability factors (unrelated to the proposed action) that were applicable to the species. These included, but were not limited to:

- Species and population status trends (e.g., declining, increasing, stable, unknown)
- Resilience of species related to number and extent of population(s) (e.g., small, fragmented, isolated population(s) vs. wide-ranging, well-connected population(s))
- Sensitivity to stochastic events
- Numbers of individuals within a population or species (low vs high numbers)

¹ In some cases, due to limited, incomplete, or potential errors in the Status of the Species section (in particular where NatureServe was the primary source of data), some of the information may be taken from other sources not presented in the SOS appendices. The majority of the sources, with very few exceptions, will be from ECOS, specifically species’ Recovery Plans, 5-Year Reviews, Listing Documents and other Service Federal Register notices.

Commented [GK4]: This document places a lot of emphasis on streamlining. It does not provide sufficient detail on how the data will be integrated in order to draw conclusions. More detail is needed to have a method that is clear, transparent and reproducible.

Commented [PM5]: The ‘approach’ as described above is too general to allow for someone to understand how calls are being made.

Commented [PA6]: If this footnote is going to be included in the BiOp, the statements re: potential errors and information w/out adequate source documentation will be a red flag for commenters.

Commented [GK7R6]: This footnote calls into question whether or not nature serve represents “best available” information.

Commented [GK8]: Of what?

Commented [PA9]: Suggest referring to BE Attachments...these are the same for all 3 chemicals.

Commented [GK10]: A full list should be provided, along with a rationale for why there were selected.

Commented [PM11]: Are these defined anywhere?

Commented [EW12]: Does this consider institutional control of the habitat or range, i.e., by public or private institutions that may be responsible for its conservation? For example, the water utility and the Moaba dace?

Due to the highly variable life histories of the species, we did not establish threshold numbers for these measures because such numbers would be highly subjective. For example, 1,000 individuals for one species may be at carrying capacity and on track for recovery, while, for another, this number may represent significant declines and recovery concerns. Life history and status also factor into the analysis. For example, species that have large, slow-growing individuals, a more advanced age at first reproduction, and with low (or no) juvenile recruitment may be highly vulnerable to stressors that further preclude juvenile survival or survival of adult females.

We made slight changes to the process for plants. Because of the large number of plant species being considered in this consultation (957), instead of selecting broad vulnerability factors for each species (as is being done for animals), each plant habitat group scorecard will report the resiliency, redundancy, and representation rankings (low, medium, high) for each species within the habitat group, as determined in the Status of the Species.

Each of these selected fields, and the associated vulnerability factors and supporting rationale are included in the Species Status section of the Scorecard.

b). Environmental Baseline and Cumulative Effects

We reviewed available information for the species or habitat group, as available, predominantly taken from Service documents on ECOS (recovery plans, 5-Year reviews, listing documents). Information related to the environmental baseline, cumulative effects, and recovery information available in these documents was used or summarized and cited. Particular attention was given to information relevant to the consultation (e.g., environmental baseline stressors related to water or habitat quality, pesticides and other contaminants, recovery actions relevant to the pilot consultations, etc.). These sections are also presented in the first section of the Scorecard.

2. Effects of the Action Summary²

This section is comprised of a brief summary of the Effects of the Action section of the biological opinion related specifically to the species (or species group, in the case of plants). The Scorecard Effects of the Action summary is a brief (one to a few paragraphs) discussion of the types of effects relevant to the species and conclusion. The summary will include:

- Aggregated magnitude of effect to the population from direct effects (mortality and sublethal effects) as produced by the MagTool or other methodology. Species that were assessed qualitatively in the BE or reside outside the lower 48 are not available for analysis within the MagTool

² We referred to this casually as the “Blue Box Effects Summary” in meetings and discussions. It is not the complete discussion of effects to a given species, which is found in the Effects of the Action section of the Opinion and its appendices.

Commented [GK13]: It would be useful if there were a decision framework for how to interpret the influence of different characteristics (vulnerability factors) on the risk conclusions. This would improve clarity on why this information is being included in the score card and how it is used.

Commented [PA14]: What is the relationship between these and the vulnerability factors in the bulleted list above?

Commented [GK15]: Is this footnote necessary?

Commented [PC16]: Is this the same as the “plant habitat” grouping?

- Indirect effects to prey items or habitat, as produced by the MagTool or other methodology.
- Risk from additional exposure routes or uses not included in aggregate, such as dermal exposure, atmospheric transport, cattle ear tags, seed treatments, granular use, bait, wide area use, and mosquito adulticide.
- Factors that would affect the likelihood of individuals being exposed, such as seasonality, pesticide persistence, and proximity of use sites to species habitat and sensitive areas. In some cases, the MagTool can be modified to account for these factors where applicable.
- Where known, factors that drive the risk, such a particular use.

Commented [PM17]: These are not 'exposure routes'

Where certain types of effects (or lines of evidence) are not relevant to a species, they would not need to be discussed. For example, if mortality of a given species would not occur, mortality would not be addressed, or would be dismissed with a standardized statement (e.g., we do not anticipate any individuals of this species would be experience a level of exposure to this chemical that would result in death.) The summary would be comprised of a plain language discussion of the overall effects of the action describing what types of effects are expected, along with the uses, and proportion of the population affected by direct and indirect effects. Standardized sentences will be used to the extent feasible and appropriate.

3) Conclusion and Rationale

This section will state the conclusion for the species (Jeopardy or No Jeopardy), and include the rationale that integrates the Effects Summary with the Status/Environmental Baseline/Cumulative Effects Summary. The rationale will also briefly address assumptions for the species related to overall differences between appropriate reasonable worst case scenarios and uses as allowable by the product labels. Additionally, where a given use(s) is likely to drive the Jeopardy call for a species, the rationale will clearly define the difference, and also clarify whether the other uses collectively would result in jeopardy³. The rationale format should also allow for cross-walking to assignment of RPMs/RPAs and incidental take, as applicable (e.g, the format will relate from the Effects/Conclusion Rationale to an ITS). The rationale will likely be brief (one to a few paragraphs), and will use plain language and standardized sentences, where feasible and appropriate.

Commented [PA18]: I'm not sure what this means. Is this meant to address use/usage information or PCT? If so, this would modify assumptions related to exposure, not the species per se.

Commented [EW19]: Yes – this is important for label modification – identifying the use that drives the risk

Overview of Scorecards Analysis

³ We don't want to have conservation measures suggested to address a use that is clearly jeopardy (for either RPAs or description of the action changes), but then still get to jeopardy because the other uses collectively result in jeopardy.

We are endeavoring to find ways of streamlining species to more rapidly and adequately determine the appropriate conclusion for each species. The methodology for plants is continuing to be developed, and is dependent in part on how the Plant MagTool will work (pending).

Commented [PA20]: Further clarification is needed here (obviously).

1) Consideration of Vulnerability (Animals)

Due to time limitations, we may consider which animal species can be analyzed quickly based on the species life history, status, and their anticipated vulnerability to additional stressors on the landscape⁴. We will assign species to these categories on an as-needed basis for triage purposes:

- *Category A* - species which are highly vulnerable to additional stressors (e.g., narrow endemics, low numbers of individuals/populations, declining trends, low resilience, low ability to recolonize from other populations, etc.). We anticipate that some of these species may be unable to lose a few (or even a single) individuals over the duration of the proposed action.
- *Category B* - species which are less vulnerable to additional stressors (e.g., species likely to be delisted in the foreseeable future, large numbers of individuals in multiple populations or widespread ranges, etc.). These species may be able to absorb losses of larger numbers of individuals over the duration of the proposed action without affecting the jeopardy curve.

For some species, we may have relatively limited information available to form assumptions about their vulnerability. For these species, we may frequently choose to reassign these species to Category A to be adequately conservative, particularly where assumptions about their distribution (e.g., rare, declining, etc.) or other life history suggest they may be highly vulnerable.

Commented [GK21]: This applies to a population trajectory, not a distribution.

Commented [PA22]: In this case, I agree it makes sense to assign to Category A. In the absence of any information, suggest creating a Category C of "unknown" rather than assuming high vulnerability.

Species can be sorted relatively quickly into these categories once vulnerability factors have been assigned (ongoing, nearing completion). It should be noted that assignment to these categories does not automatically indicate that a conclusion of jeopardy or no jeopardy is applicable. Species in Category B, for example, may still be susceptible to a high degree of effects from the Proposed Action. However, we recognize the loss of a small number of individuals will likely be more important to species in Category A vs. Category B. We do not anticipate Category assignments to be reflected in the Scorecards, but instead serve as a streamlining tool for the I&S process.

2) Triage (Animals)

⁴ This likely vulnerability ranking is separate from the analysis performed related to the Effects of the Action, and is based on considerations from the Status of the Species, Environmental Baseline and Cumulative Effects.

To the extent possible, we will determine which species are suitable for streamlined conclusion decisions. In some cases, we will not need to complete a full and detailed analysis where an appropriate conclusion of either No Jeopardy or Jeopardy is clearly warranted. While the Effects of the Action would still be integrated with the Status of the Species, the Environmental Baseline and Cumulative Effects, we will use a rapid analysis process in these cases.

One rapid analysis method would be related to the vulnerability categories described earlier. For example:

- For species falling under Category A (as described above), we would closely consider the likelihood of mortality and sublethal effects for even a few individuals. This would be particularly true where any of the following ~~are true~~ are applicable:
 - species exists in one population or very few populations;
 - where populations were fragmented or isolated such that sufficient recolonization would be difficult or unlikely in the event of the loss of a population (or a substantive portion of the population, a highly variable and in some cases qualitative estimate depending, on the best available information for the species);
 - narrow endemics

For this category of species, if the effects of the action would result in mortality to even a few individuals where such loss could not be absorbed, we can use a streamlining method. In these cases, the draft conclusion would likely be a “jeopardy” call.

- For species falling under Category B, where (1) effects of the action are expected to be lower related to exposure and/or magnitude of response, relative to the size and distribution of the populations, and (2) other factors on the landscape (per the Environmental Baseline and Cumulative Effects) are exhibiting less serious pressures on the species.

For this category of species, if the effects of the action will be relatively minimal (e.g., have lower toxicity, lower risk of exposure, lower magnitude of effect), for species where the other stressors on the landscape and status of the species are of less concern (i.e., species that are less vulnerable due to widespread presence, higher numbers, stable or increasing populations, etc.), we can also use a similar streamlining method. In these cases, the draft conclusion would likely be a “no jeopardy” call.

Commented [PM23]: There has to be some link between individual effects and population-level effects. Otherwise, the process is not transparent or predictable. Additionally, it's required to set meaningful mitigations.

Another method could be used for any species—not just those in the Categories above—and is related to toxicity of the pesticide and the anticipated magnitude of effect (i.e., mortality). For example:

- Species that are anticipated to be highly sensitive to the effects of the pesticide, where any individuals exposed would be anticipated to die due to acute lethal effects.
 - In this case, we would not do a full analysis of sublethal effects to the species in the I&S (although the information would still be generated in the MagTool runs and other results).
 - We would still consider indirect effects, such as forage base, host plants, host fish, pollinators, etc., for individuals that would not be exposed.

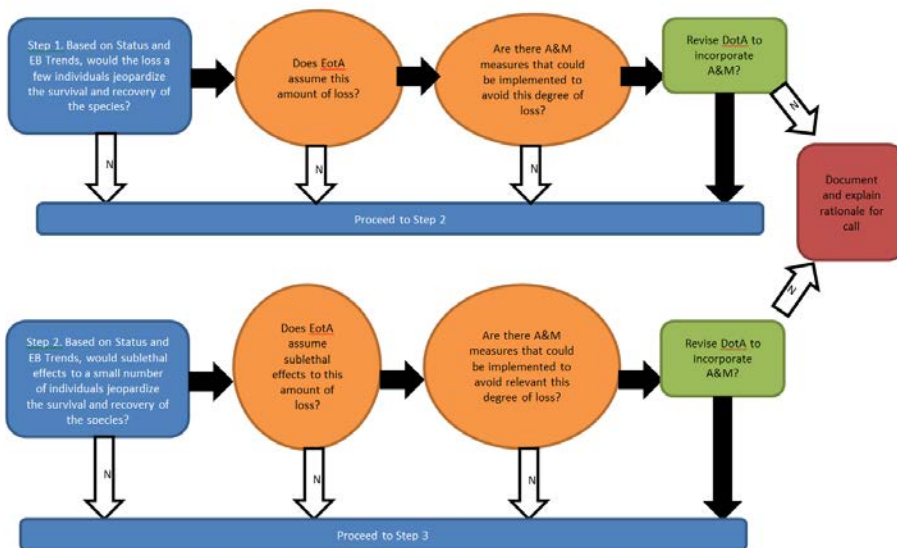
Commented [PM24]: We tried to do this in the BE (i.e., stop at mortality but they insisted that they needed information related to ALL of the lines of evidence).

Commented [PA25R24]: If we can agree on this point moving forward, it will save us time/resources in earlier steps.

In Figure 1 below, we present an illustration of how one of the triage methods described above—the Category A high vulnerability example—might be used. Instead of a full analysis, we would perform a quick qualitative review of the Category A species, which in some cases we may find would not be able to absorb the loss of even a few individuals to either mortality (in step 1) or sublethal (in step 2). In these cases, the draft conclusion would likely be a “jeopardy” call.

Figure 1. Example of streamlining of the process as it would apply to highly vulnerable species. The (EB = Environmental Baseline; EotA = Effects of the Action; A&M = avoidance and minimization measures; DotA = Description of the Action)

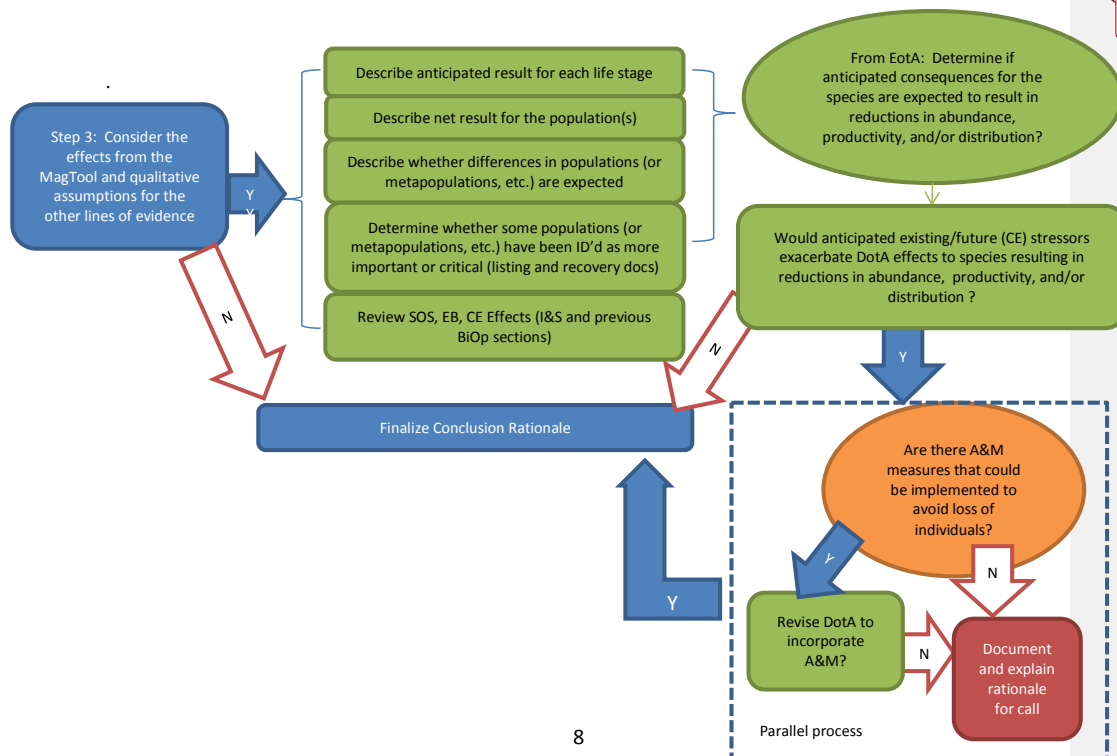
Commented [PM26]: You probably should avoid using ‘Step 1’, ‘Step 2’, etc... since it might be confused with our 3-step consultation process.



3) Non-Streamlined Steps

For the remaining species (e.g., in the absence of off ramps), an abbreviated but more complete analysis would be conducted, generally following Step 3 in Figure 2 below. This analysis will resume the process by considering the outputs from the Magtool and other considerations as described in the Effects of the Action framework. All of the lines of evidence established in the BE and draft Opinion (e.g., other sublethal effects, indirect effects, etc.) would be considered for the species. Finally, additional qualitative considerations related to other factors~~uses~~ (e.g., mixtures) would be considered. The statements above related to effects to life stages, then stepped up to populations and the overlap with Status of the Species, Environmental Baseline and Cumulative Effects would be evaluated as well similarly for these types of effects and considerations.

Figure 2. Example of process considering species. (EB = Environmental Baseline; EotA = Effects of the Action; A&M = avoidance and minimization measures; DotA = Description of the Action)



Commented [PM27]: This provides information on what you plan to do... but not HOW you plan to do it.

Commented [PA28]: Agreed. I'm still unclear how these factors are weighted in determining J/NJ

EXAMPLE SCORECARD

The Integration and Synthesis Summaries for each species (“Scorecard Summaries”) would consist of the various components of the analysis added together in a brief multi-page document for each species. The scorecard follows these basic headings:

- Status of the Species/Environmental Baseline/Cumulative Effects (i.e., species background)
 - Species status, vulnerability ranking, stressors
 - Combined environmental baseline and cumulative effects summary
 - Abridged recovery overview
- Effects of the Action Summary
 - Overview of effects to individuals and types of relevant uses
 - Summary of mortality and sublethal outputs from the MagTool (as available/appropriate)
 - some species were not modeled in the MagTool ~~due to modeling limitations~~, such as marine mammals, cave invertebrates, etc.
 - Other uses not addressed in the MagTool, as applicable (seed treatment, granular, bait, of mosquito adulticide, wide-area uses, etc.)
 - Other lines of evidence (e.g., mixtures, abiotic, etc.) – likely to be standardized text for many species
- Conclusion Summary
 - Draft Jeopardy or No Jeopardy conclusion
 - Rationale – will cover the most important factors relative to a species:
 - Ties together species background information with the Effects of the Action.
 - Will use standardized text to the extent possible

An example draft scorecard for Malathion is provided below, in the form of screenshots from a species currently being evaluated (Karner blue butterfly). NOTE: The analysis for this species is still being finalized, so the information in any of the fields may change prior to the draft biological opinion. While this species has numerous populations, other factors such as its precipitous decline, isolated populations, small number of individuals in one or more populations and sensitive to stochastic events would likely warrant its inclusion in the Category A species grouping as described above.

Figure 3a: Draft Example Species Scorecard (Part 1). The initial section of the scorecard, showing status of the species highlights together with applicable vulnerability factors and stressors. The next portion of this section is titled at the bottom of the page ("Environmental Baseline/Cumulative Effects Summary"), which continues as Figure 3b.

Commented [PC29]: It's not clear what the higher and moderate terms mean in the vulnerability factors box mean. Higher than other species?

Commented [PM30]: For the 'Vulnerability Factors' – how are these defined?

Commented [PM31]: How can you have 'relatively stable' species level trends if the population trends are declining 70-90%?

Integration and Synthesis Summary:

Species:	<i>Lycaeides melissa samuelis</i>	Entity ID:	420
	Karner blue butterfly		

Summary of Status, Environmental Baseline, and Cumulative Effects

Species Level Trends	Relatively stable (NatureServe, 2015)	Number of Populations	114 - 116 (USFWS, 2012)
Population Level Trends	Decline of 70 - 90% (NatureServe, 2015)	Population Size	2500 - 10,000 individuals (NatureServe, 2015)

DRAFT

Population Narrative Severe decline started in 1970's, 1987 - 1988 droughts finished off numerous remnant demes. Most current EOs (D-ranked) expected to be lost. Much habitat lost before 1970. No chance of survival now without management. This species has experienced a long-term decline of 70-90%. The species has stabilized somewhat with federal listing. The estimated population size is 2,500 - 10,000 (NatureServe, 2015). Research by Fuller (2008) suggests that a minimal viable population of KBBs should be a first and second brood average of 7,641-12,960 adults, or 11,217- 19,025 second brood adults, maintained on average over five or more years and the average KBB number should fall within these ranges every year. Based on available information there were 114 and 116 KBB populations or sites in 1992 and 2011, respectively (USFWS, 2012).

References NatureServe. 2015. *NatureServe Central Databases. FSTF received dataset on 08_11_2015. Arlington, Virginia, U.S.A.; USFWS 2012. Karner Blue Butterfly (Lycaeides melissa samuelis) 5-Year Review: Summary and Evaluation. U.S. Fish and Wildlife Service Ecolo*

Vulnerability Factors and Indicator	420 <i>Lycaeides melissa samuelis</i>
Small, endemic, constrained, and/or isolated population(s)	Higher
Small number of individuals in one or more populations	Higher
Sensitive to stochastic events (natural and/or anthropogenic)	Higher
Contaminants (including but not limited to pesticides) noted as a stressor or threat in listing and/or recovery documents	Higher
Multiple populations (few)	Moderate
All populations stable, with none known to be increasing or decreasing	Moderate
Unknown reproductive rate	Unknown

Stressor	<i>Lycaeides melissa samuelis</i>
Habitat loss and degradation (NatureServe, 2015; USFWS, 2012)	
Small population size/stochastic events (NatureServe, 2015; USFWS, 2012)	
Disease and predation (USFWS, 2012)	
Inadequacy of existing regulatory mechanisms (USFWS, 2012)	
Pesticide use (USFWS, 2012)	
Hybridization (USFWS, 2012)	
Climate change (USFWS, 2012)	

Rationale Related to Vulnerability

Karner blue butterflies historically occurred in savanna and barrens habitats typified by dry sandy soils, and now occur in remnants of these habitats, as well as other locations such as roadsides, military bases, and some forest lands (Recovery Plan, 2003). The rangewide number of KBB populations or sites has remained generally the same since listing (1992), however, particular sites may have low numbers of individuals or may be decreasing in size. In addition, the KBB is believed to be extirpated from Minnesota and possibly Indiana (USFWS, 2012, Jill Utrop USFWS 2016 EPA biological information field ask). Overall, KBB populations are fragmented and tend to be isolated. Spatial distribution at the metapopulation level has improved at some KBB recovery sites as a result of habitat restoration and management, but habitat degradation and loss from succession and invasive plants remain primary threats to the species at all recovery sites (USFWS, 2012). Because of the fragmented nature of KBB habitat and their poor dispersal ability, stochastic events are also considered a threat to the species.

Environmental Baseline/Cumulative Effects Summary

Figure 3b: Draft Example Species Scorecard (Part 2). The middle section of the scorecard, showing the text of the Environmental Baseline/Cumulative Effects Summary and recovery information, followed by the start of the Summary of Effects (“blue box effects summaries”). Additional effects summary text are continued in Figure 3c.

<p>The historical range of the KBB in the United States has not changed although changes in the distribution of the KBB within its historic range have occurred since listing (USFWS, 2012). The Karner blue butterfly, <i>Lycaeides melissa samuelis</i>, formerly occurred in a band extending across 12 states from Minnesota to Maine and in the province of Ontario, Canada (USFWS, 2003). The KBB should continue to remain listed as endangered because of the populations at some recovery areas (in New York, Indiana, Michigan, and Minnesota) have remained low or are demonstrating a decline. In addition, major threats have not been ameliorated and the criteria for down listing to threatened has not been met. Declining populations and loss of habitat in Minnesota, Indiana, and New York are not compensated for by the more numerous populations in Wisconsin and Michigan. Threats persist for the KBB in all states including loss of habitat due to natural succession, lack of management, invasive species and commercial, industrial and residential development. Threats related to global climate change appear to already be occurring with the presence of third brood KBBs noted in most states in 2010, and more severe threats will likely be realized in the coming decades. In sum, our current understanding of the KBB's status leads us to conclude that this species continues to face a probability of extinction throughout all or a significant portion of its range, thereby meeting the definition of endangered under the Endangered Species Act</p>		
EB/CE Source	5 year review, 2012, USFWS	
Recovery Summary	Species' Recovery Priority Number at start of 5-year review: 9 C (indicating a subspecies with a moderate degree of threat and high potential for recovery, and in conflict with construction or other development projects or other forms of economic activity).	Applicable Recovery Action
		1. Protect and manage Karner blue and its habitat to perpetuate viable metapopulations. 2. Evaluate and implement translocation where appropriate. 3. Develop statewide and regional management guidelines. 4. Develop and implement information and education program. 5. Collect important ecological data on Karner blue and associated habitats. 6. Review and track recovery progress (includes re-evaluation of recovery goals for Wisconsin)
Recovery Info Source	2003 USFWS Recovery Plan, 5-year review 2012	
Other Relevant Notes		
<p>In typical years, first brood larvae (caterpillars) hatch from overwintered eggs in mid- to late April and begin feeding on wild lupine (<i>Lupinus perennis</i>), the only known larval food source (Figure 2). Larvae pass through four instars (developmental stages), between which the relatively soft larval exoskeleton is shed. Feeding by first and second instar larvae results in tiny circular holes in the lupine leaves while older larvae eat all but the upper or lower epidermis, creating a characteristic window-pane (Figure 1) appearance (e.g., Swengel 1995). Larvae feed for about three to four weeks and pupate (transform from larvae to adult) in late May to early June. Ants commonly tend larvae.</p>		
Summary of Effects of the Proposed Action		
Likelihood of Exposure		
<p>Within the range of the Karner Blue Butterfly (consisting of 37 counties among 7 states), the use categories are mosquito adulticide, pasture, corn, open space developed, developed, wheat, vegetables and ground fruit, other row crops, other grains, orchards and vineyards, Christmas trees, and other crops. The total for percent overlap for all uses (less mosquito adulticide) is approximately 37 % with individual use sites ranging from 0.009% for other row crops to 15.3% for pasture.</p> <p>The Karner Blue is known to frequent roadsides, military bases, and forests in search of the nectar/pollen from a nectar plant during the adult stage and may be more likely to be exposed to pesticide use in these scenarios.</p> <p>The Karner blue butterfly usually has two generations, and thus two hatches, each year. In April, the first group of caterpillars hatch from eggs that were laid the previous year (overwintered eggs). These individuals mature and lay eggs in June on or near wild lupine plants, which become the second generation of adult butterflies appearing in July. These adults mate and lay eggs that will not hatch until the following spring. Therefore, the Karner Blue Butterfly is vulnerable to the effects of malathion throughout its entire lifecycle, especially vulnerable are the larval and adult stages if applications are made from April through July.</p>		

DRAFT

Commented [PM32]: Vitalization section below... why are Hawaiian cloud forests being discussed with the KBB (it's not at all relevant to KBB habitat)?

Commented [PA33R32]: And the discussion re: Central Valley, Sierras in CA is also not relevant for this species.

Commented [PM34]: Second paragraph below in blue box – does malathion have roadside, military base, or forestry uses?

Commented [PM35]: There are inconsistencies in this write-up... e.g., it's stated that the species is extirpated from MN, but MN still appears to be in the range in this part of the discussion.

Commented [CJ36]: How is the total percent overlap excluding adulticide being calculated? Overlap numbers should be reported to the thousandth decimal place

Figure 3c: Draft Example Species Scorecard (Part 3). The next screenshot of the scorecard, showing the much of the remaining summary text of the Effects of the Action. Remaining summary text is continued in Figure 3d.

<p>Risk to individual if exposed</p> <p>100% mortality to exposed individuals within a population of Karner Blue Butterflies is expected across all crop types. Based on the Weight of Evidence from the BE, we have high confidence in this estimate of risk to individuals within a population.</p> <p>Mortality Line of Evidence (Mag Tool Output)</p> <p>Populations exposed to malathion on sites of application will experience <37.6% mortality at the maximum application rates and exposed via spray drift at the maximum application rates would experience 57.3% mortality each</p> <p>Sublethal (MagTool Output)</p> <p>NA</p> <p>Indirect Effects (MagTool Output)</p> <p>The dietary items for this species include grass (the larval stage of this species consumes only leaves from the host plant, wild lupine, <i>Lupinus perennis</i> L. (Fabaceae), which it has an obligate relationship) and nectar/pollen from other sources (which this species relies on during the adult stage). Approximately 1/3 of the uses associated with the overlap within the Karner Blue range will cause a decline in growth of plant food sources, impacting the ability of the Karner Blue Butterfly to consume enough food during larval or adult stages.</p> <p>Volatilization</p> <p>Organophosphate pesticides are volatile and able to vaporize from sprayed fields and orchards continuously after application. Deposition can be expected to occur beyond the 1,000ft buffer modeled and described as the action area. Additionally, volatilization can occur from lowland organophosphate application and drift sites and be deposited within cloud and fog zones in the form of condensation, fog drip, and rainfall at higher elevations (e.g., the cloud zone of the main Hawaiian islands is ~1600-9300ft elevation). As a result, exposure is expected to occur outside the use sites and modeled spray drift areas, increasing the spatial range that would be exposed. Impacted areas at higher elevations are most likely to include areas with persistent trade winds, cloud formations, and rain on the high islands such as in Hawaii, California's Central Valley, and Sierra Nevada mountains of California. However, the magnitude of increased exposure is uncertain due to the unpredictability of weather events, along with variability of the geographical features across the landscapes that influence transport and deposition.</p> <p>Dermal</p> <p>NA</p> <p>Mosquito Adulticide</p> <p>The malathion label allows for mosquito adulticide application at any location at a maximum frequency of once a week. While the entire range of Karner Blue Butterfly could be exposed to this use, we do not expect that mosquito adulticide usage will be either this expansive or frequent. However each spray is likely to result in 100% mortality for exposed individuals.</p> <p>Mixtures Line of Evidence</p> <p>Exposure to mixtures through formulated products, tank mixes, and environmental mixtures is expected to cause increased toxicity to the Karner Blue Butterfly compared to exposure to the active ingredient alone. In general, the magnitude of that increase is uncertain because the composition of mixtures and concentrations of the degradates in the environment is usually not known.</p>	<p>Commented [PA37]: I may be opening a can of worms here, but the assumption of max application via spray drift is only relevant for the edge of treated site – dissipation occurs with distance from the treated application site. Malathion causes an impact in the decline of plant food sources? What did we say about mixtures in the BE – is this statement supported by actual data or is this the default language?</p> <p>Commented [PC38]: I think the language on mortality exposed to onsite and offsite needs to be clarified to indicate it's based on the overlap analysis. It kinda sounds like if the species were on a treated site, only 37% would die, as opposed to indicating that the uses on sites that overlap with the species range will result in 37% death.</p> <p>I would change the language about volatility. OPs are semivolatile.</p>
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Figure 3d: Draft Example Species Scorecard (Part 4). The final summary text of the Effects of the Action for this species, followed by the conclusion and rationale.

Abiotic Line of Evidence The effects to an individual Karner Blue described by other lines of evidence could be greater when accounting for deviations in temperature. There is uncertainty regarding the range of temperatures relevant to individual species that are sufficient to alter toxicity of the chemical, as well as the magnitude of any potential effects.	
Summary of Rationale for Conclusion	
Conclusion (Malathion):	After reviewing the current status of the listed species and designated critical habitat, the environmental baseline for the action area, the effects of the proposed registration of Malathion, and the cumulative effects, it is the Service's Biological Opinion that the registration of Malathion, as proposed, is likely to jeopardize the continued existence of the Karner Blue Butterfly.
Rationale:	While the species is comprised of numerous populations, and habitat restoration and management has occurred in some areas, this species nonetheless remains extremely vulnerable to additional threats due to its small, isolated, and fragmented populations. The use of Malathion, as allowed by the labeled uses, is anticipated to kill all individual butterflies directly exposed during application. Based on the overlap analysis, when a population is exposed, we anticipate 37.6% of the population will die. An additional 57.3 % of the population will die from drift associated with that application. Application of Malathion as allowed by the label will also result in indirect effects, reducing growth rates of the species' host plant, the wild lupine, <i>Lupinus perennis</i> L. (Fabaceae), which will impact the ability of individuals of the species to consume enough food during critical larval and adult life stages. Other factors, such as frequency of applications, volatility, the use of adulticides (which have much broader usage), mixtures, and temperature could increase the effects to the populations, and in some cases, the number of populations affected. While we recognize not all populations are likely to be affected directly or indirectly by the use of Malathion products over the duration of the action, we do anticipate that multiple populations will be affected, resulting in the loss of large proportions of the affected populations (when accounting both for individuals in the areas of application and drift), which are unlikely to be recolonized due to the isolated and fragmented nature of the populations. In the absence of protective buffers or other specific protective measures, we anticipate multiple populations will be lost over the duration of the proposed action. Furthermore, in the absence of any proposed monitoring of applications of Malathion products within the range of the species, it will be impossible to determine how many populations are exposed. Thus, the anticipated direct and indirect effects of the action, combined with the effects of interrelated and interdependent actions, and the cumulative effects associated with future State, Tribal, local, and private actions will appreciably reduce the likelihood of survival and recovery of the species. The anticipated direct and indirect effects of the action will measurably reduce Karner blue butterfly survival, numbers, and distribution at the scale of the range of the species.
<div style="background-color: red; color: white; padding: 5px; display: inline-block;">DRAFT</div>	
Critical Habitat Conclusion	The Karner blue butterfly does not have designated critical habitat, so no destruction or adverse modification of critical habitat for this species will occur.
Rationale:	

Commented [PM39]: •The statement, “Based on the overlap analysis, when a population is exposed, we anticipate 37.6% of the population will die” is an oversimplification that is not defensible. Remember the assumptions... if malathion is applied to all potential use sites at maximum application rates and KBB are evenly distributed throughout their range, there is a potential for up to 38% of individuals to die from malathion use – that’s what the MAG tool is telling you. The next question is, does that represent a population-level effect that would or would not result in jeopardy. For mitigation purposes... what is the level of mortality that could be tolerated by the population?

Commented [PA40R39]: Agreed. And the statement re: 57.3% of population will die from drift is also inaccurate. Still unclear about the reduced growth in the host plant.

Commented [PM41]: This comes down to a ‘gut check’ unless there are some clearly defined criteria for how the decisions are made... you are clearly making decisions – what criteria are you using to make them?

Integration and Synthesis Summary: Insects

MALATHION - DRAFT

Family	Lycaenidae	Species:	Lycaeides melissa samuelis	Karner blue butterfly	Entity ID:	420
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Summary of Status, Environmental Baseline, and Cumulative Effects

Species Level Trends	Relatively stable (NatureServe, 2015)	Number of Populations	114 - 116 (USFWS, 2012)
Population Level Trends	Decline of 70 - 90% (NatureServe, 2015)	Population Size	2500 - 10,000 individuals (NatureServe, 2015)

Population Narrative Severe decline started in 1970's, 1987 - 1988 droughts finished off numerous remnant demes. Most current EOs (D-ranked) expected to be lost. Much habitat lost before 1970. No chance of survival now without management. This species has experienced a long-term decline of 70-90%. The species has stabilized somewhat with federal listing. The estimated population size is 2,500 - 10,000 (NatureServe, 2015). Research by Fuller (2008) suggests that a minimal viable population of KBBs should be a first and second brood average of 7,641-12,960 adults, or 11,217- 19,025 second brood adults, maintained on average over five or more years and the average KBB number should fall within these ranges every year. Based on available information there were 114 and 116 KBB populations or sites in 1992 and 2011, respectively (USFWS, 2012).

References NatureServe. 2015. NatureServe Central Databases. FSTF received dataset on 08_11_2015. Arlington, Virginia, U.S.A.; USFWS 2012. Karner Blue Butterfly (Lycaeides melissa samuelis) 5-Year Review: Summary and Evaluation. U.S. Fish and Wildlife Service Ecolo

Vulnerability Factors and Indicator	420-Lycaeides-melissa-samuelis	Stressor	Lycaeides-melissa-samuelis
Small, endemic, constrained, and/or isolated population(s)	Higher	Habitat loss and degradation (NatureServe, 2015; USFWS, 2012)	
Small number of individuals in one or more populations	Higher	Small population size/stochastic events (NatureServe, 2015; USFWS, 2012)	
Sensitive to stochastic events (natural and/or anthropogenic)	Higher	Disease and predation (USFWS, 2012)	
Contaminants (including but not limited to pesticides) noted as a stressor or threat in listing and/or recovery documents	Higher	Inadequacy of existing regulatory mechanisms (USFWS, 2012)	
Multiple populations (few)	Moderate	Pesticide use (USFWS, 2012)	
All populations stable, with none known to be increasing or decreasing	Moderate	Hybridization (USFWS, 2012)	
Unknown-Reproductive rate	Unknown	Climate change (USFWS, 2012)	

Rationale Related to Vulnerability

Karner blue butterflies historically occurred in savanna and barrens habitats typified by dry sandy soils, and now occur in remnants of these habitats, as well as other locations such as roadsides, military bases, and some forest lands (Recovery Plan, 2003). The rangewide number of KBB populations or sites has remained generally the same since listing (1992), however, particular sites may have low numbers of individuals or may be decreasing in size. In addition, the KBB is believed to be extirpated form Minnesota and possibly Indiana (USFWS, 2012, Jill Utrop USFWS 2016 EPA biological information field ask). Overall, KBB populations are fragmented and tend to be isolated. Spatial distribution at the metapopulation level has improved at some KBB recovery sites as a result of habitat restoration and management, but habitat degradation and loss from succession and invasive plants remain primary threats to the species at all recovery sites (USFWS, 2012). Because of the fragmented nature of KBB habitat and their poor dispersal ability, stochastic events are also considered a threat to the species.

Environmental Baseline/Cumulative Effects Summary

- Commented [GK1]: The score card should include the BE's call (LAA/NLAA) for the species and the critical habitat (if applicable).
- Commented [GK2]: This document leaves out important data that are necessary to evaluate the risk picture. For instance, toxicity values, application rates. Where will these information be described?
- Commented [PM3]: I'm a little confused... how can the 'species level' be stable, but the populations are declining by 70 - 90%?
- Commented [GK5]: Is this total number of individuals in the species or number of individuals per population?
- Commented [GK4]: The use of the term "population" is confusing here. Is this the total number of individuals in the species or in specific populations?
- Commented [GK6]: What is this?
- Commented [GK7]: Spell out acronyms
- Commented [GK8]: What is this?
- Commented [GK9]: Of the species?
- Commented [GK10]: Since 1970?
- Commented [GK11]: This is incomplete. For example, USFWS 2003 is not included here.

The historical range of the species in the United States has not changed although changes in the distribution of the species within its historic range have occurred since listing (USFWS, 2012). The species formerly occurred in a band extending across 12 states from Minnesota to Maine and in the province of Ontario, Canada (USFWS, 2003). The species should continue to remain listed as endangered because of the populations at some recovery areas (in New York, Indiana, Michigan, and Minnesota) have remained low or are demonstrating a decline. In addition, major threats have not been ameliorated and the criteria for down listing to threatened has not been met. Declining populations and loss of habitat in Minnesota, Indiana, and New York are not compensated for by the more numerous populations in Wisconsin and Michigan. Threats persist for the species in all states including loss of habitat due to natural succession, lack of management, invasive species and commercial, industrial and residential development. Threats related to global climate change appear to already be occurring with the presence of third brood noted in most states in 2010, and more severe threats will likely be realized in the coming decades. In sum, our current understanding of the species' status leads us to conclude that this species continues to face a probability of extinction throughout all or a significant portion of its range, thereby meeting the definition of endangered under the Endangered Species Act.

EB/CE Source	5 year review, 2012, USFWS		
Recovery Summary	Species' Recovery Priority Number at start of 5-year review: 9 C (indicating a subspecies with a moderate degree of threat and high potential for recovery, and in conflict with construction or other development projects or other forms of economic activity).	Applicable Recovery Action	1.Protect and manage Karner blue and its habitat to perpetuate viable metapopulations. 2. Evaluate and implement translocation where appropriate. 3. Develop rangewide and regional management guidelines. 4. Develop and implement information and education program. 5. Collect important ecological data on Karner blue and associated habitats. 6. Review and track recovery progress (includes re-evaluation of recovery goals for Wisconsin)
Recovery Info Source	2003 USFWS Recovery Plan, 5-year review 2012		

Other Relevant Notes (if any):

In typical years, first brood larvae (caterpillars) hatch from overwintered eggs in mid- to late April and begin feeding on wild lupine (*Lupinus perennis*), the only known larval food source (Figure 2). Larvae pass through four instars (developmental stages), between which the relatively soft larval exoskeleton is shed. Feeding by first and second instar larvae results in tiny circular holes in the lupine leaves while older larvae eat all but the upper or lower epidermis, creating a characteristic window-pane (Figure 1) appearance (e.g., Swengel 1995). Larvae feed for about three to four weeks and pupate (transform from larvae to adult) in late May to early June. Ants commonly tend larvae.

Summary of Effects of the Proposed Action

Likelihood of Exposure

Within the range of the Karner blue butterfly (consisting of 37 counties among seven states), the use site categories are mosquito adulticide, pasture, corn, open space developed, developed, wheat, vegetables and ground fruit, other row crops, other grains, orchards and vineyards, Christmas trees, and other crops. The total percent overlap for all uses (except mosquito adulticide) is approximately 37 %. The percent overlap for individual use sites range from a low of 0.009% (other row crops) to a high of 15% (pasture).

The Karner blue butterfly is known to frequent roadsides, military bases, and forests in search of the nectar/pollen from a nectar plant (Recovery Plan 2003) during the adult stage and may be more likely than a larvae to be exposed to pesticide use in these scenarios.

The Karner blue butterfly usually has two generations, and thus two hatches, each year. In April, the first group of caterpillars hatch from eggs that were laid the previous year (overwintered eggs). These individuals mature and lay eggs in June on or near wild lupine plants, which become the second generation of adult butterflies appearing in July. These adults mate and lay eggs that will not hatch until the following spring. April through July is the height of breeding and feeding activity for these butterflies, therefore, the Karner blue may be more vulnerable to the effects of malathion during the larval and adult stages if applications are

Commented [PM12]: There are inconsistencies in the range information (e.g., no longer in MN – see above – but say in MN here – and says 37 counties and 7 sates below). Looks like different range information is being used for the different ‘sections’.

Commented [GK13]: Information on adult diet and number of life cycles per year should be included here. These factors influence exposure discussed below.

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Commented [PM14]: Where are the figures referred to here?

made from April through July, however it is potentially exposed throughout its entire lifecycle.

Risk to individual(s) if exposed

We anticipate 100% mortality to any individuals within a population of Karner blue butterflies exposed to malathion. This high degree of mortality is expected across all crop types. Based on the Weight of Evidence information from the BE, we are very confident (high confidence) in this estimated risk to individuals within a population.

Mortality Line of Evidence (Mag Tool Output)

Populations exposed to malathion on sites of application will experience on average 38% mortality to individuals as per the label maximum application rates. Populations exposed adjacent to the sites of application via spray drift as per the label maximum application rates would experience 57% mortality each year.

Sublethal (MagTool Output)

A high percent mortality is expected in populations exposed, therefore it is unlikely there will be survivors to experience sublethal impacts.

Indirect Effects (MagTool Output)

The dietary items for this species include grass (the larval stage of this species consumes only leaves from the host plant, wild lupine, *Lupinus perennis* L. (Fabaceae), which it has an obligate relationship) and nectar/pollen from other sources (which this species relies on during the adult stage). Approximately one-third of the uses associated with the overlap within the Karner blue butterfly range will cause a decline in growth of plant food sources, impacting the ability of the Karner blue butterfly to consume enough food during larval or adult stages

Volatilization

We do not expect transport from volatilization to be an appreciable source of exposure for this species.

Dermal

The dermal route of exposure is already assessed by the MagTool for all chemicals for terrestrial invertebrates.

Mosquito Adulticide (MagTool Output)

The malathion label allows for mosquito adulticide application at any location at a maximum frequency of once a week. While the entire range of the Karner blue butterfly could be exposed to this use, we do not expect that mosquito adulticide usage will be either this expansive or frequent. However each spray is likely to result in 100% mortality for exposed individuals.

Mixtures Line of Evidence

See section General Effects

Abiotic Line of Evidence

See section General Effects

Summary of Rationale for Conclusion

Commented [PA15]: Are there any specific malathion toxicity data for Lepidoptera or is the endpoint based on bee data?

Commented [GK16]: How many individuals are exposed?

Commented [GK17]: The terminology in this box does not make sense. Perhaps the first sentence should read: "we anticipate that 100% of individuals exposed to malathion will die."

Commented [PM18]: It's not clear from this write-up that there is a clear understanding of what the MAG-tool outputs mean.

Commented [PM19]: I don't think it's true that you would expect mortality to ALL individuals exposed to ANY level of malathion... at what concentration would you expect 100% of the individuals exposed to die?

Commented [GK20R19]: I agree. If this were the case, the species would be extinct. Clearly, only a portion of the population is exposed in any given year. There is a need to consider the percent of the potential use sites that are being treated.

Commented [PA21]: How does this % vary across different use patterns with different application rates and different percentages of overlap w/the range. And why is mortality from drift higher than the on-site number?

Commented [PM22]: I think what they are trying to say is that if exposure occurs at concentrations high enough to result in any potential effects, death is the most likely effect? This is worded strangely here.

Commented [PM23]: Lupine is not a grass. The broad-leaf food category should be used. Additionally, this makes it sound like about 1/3 of the uses will cause growth declines in all of the plant food sources in the KBB range – I don't think that is true.

Commented [GK24]: What is the basis for this conclusion?

Commented [GK25]: This term does not apply to insects. Suggest using "contact" instead

Commented [PA26]: If already assessed, is there a need to have a separate heading?

Commented [GK27]: The MagTool assesses contact and dietary based exposure to inverts.

Conclusion (Malathion):

After reviewing the current status of the listed species and designated critical habitat, the environmental baseline for the action area, the effects of the proposed registration of malathion, and the cumulative effects, it is the Service's Biological Opinion that the registration of malathion, as proposed, is likely to jeopardize the continued existence of the Karner Blue Butterfly.

Rationale:

While the species is comprised of numerous populations, and habitat restoration and management has occurred in some areas, this species nonetheless remains extremely vulnerable to additional threats due to its small, isolated, and fragmented populations. The use of malathion, as allowed by the labeled uses, is anticipated to kill all individual butterflies directly exposed during application. Based on the overlap analysis, when a population is exposed, we anticipate 38% of the population could die. An additional 57% of the population could die from drift associated with that application. Thus, we anticipate that up to 95% of an exposed population would be lost. Application of malathion as allowed by the labels would also result in indirect effects, reducing growth rates of the species' host plant, the wild lupine, *Lupinus perennis* L. (Fabaceae), which would impact the ability of individuals of the species to consume enough food during critical larval and adult life stages. Other factors, such as frequency of applications, volatility, the use of adulticides (which have much broader usage), mixtures, and temperature could increase the effects to the populations, and in some cases, the number of populations affected.

While we recognize not all populations are likely to be affected directly or indirectly by the use of malathion products over the duration of the action, we do anticipate that multiple populations will be affected, resulting in the loss of large proportions of the affected populations (when accounting both for individuals in the areas of application and drift), which are unlikely to be recolonized due to the isolated and fragmented nature of the populations. In the absence of protective buffers or other specific protective measures, we anticipate multiple populations will be lost over the duration of the proposed action. Furthermore, in the absence of any proposed monitoring of applications of malathion products within the range of the species, it will be impossible to determine how many populations are exposed.

Thus, the anticipated direct and indirect effects of the action, combined with the effects of interrelated and interdependent actions, and the cumulative effects associated with future state, tribal, local, and private actions will appreciably reduce the likelihood of survival and recovery of the species. The anticipated direct and indirect effects of the action will measurably reduce Karner blue butterfly survival, numbers, and distribution at the scale of the range of the species.

Critical Habitat Conclusion:

Critical habitat has not been designated for this species.

Rationale: not applicable

Commented [GK28]: According to text below, there is no critical habitat for this species.

Commented [PA29]: What RPAs / RPMs would be proposed? FYI – we have an existing Bulletin for this species (developed for methoxyfenozide) in WI and MI I think. Use is prohibited in areas w dry sandy soils supporting lupine.

Commented [GK30]: The major uncertainties associated with the analysis should also be addressed here.

Commented [GK31]: Are all 114-116 populations impacted equally? Are there some populations that are more at risk than others?

Commented [GK32]: Do the butterflies actually use malathion use sites?

Commented [GK33]: Population or species?

Commented [PM34]: This is under the assumptions that every single potential use site (except the mosquito use) is being applied at maximum application rates at the same time.... This does not pass the laugh test.

Commented [PA35]: Why volatility? It is stated above that volatilization is not expected to be appreciable source of exposure.

Commented [PM36]: Based on what?

Commented [GK37]: Use of the term "anticipate" overstates the confidence of this risk assessment. I suggest the use of more cautious language, such as "potential".

Integration and Synthesis Summary: Fishes

MALATHION - DRAFT

Family	Cyprinidae	Species:	Moapa coriacea	Moapa dace	Entity ID:	211
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Summary of Status, Environmental Baseline, and Cumulative Effects

Species Level Trends	Increasing	Number of Populations	6-20
Population Level Trends	Increasing	Population Size	A population survey in 2013 found 1,727 individuals (USFWS 2013).

Population Narrative	Based on current surveys, trends show an increase in population sizes for the species (USFWS 2013). There are currently between 6 and 20 occurrences-populations (NatureServe 2015), with a total population-numbersize of 1,727 individuals throughout their range (USFWS 2013). The species is moderately resilient, but representation and redundancy are low. Population growth rate appears to be stable. Based on the narrow range of the species, adaptability is low.
References	NatureServe. 2015. NatureServe Explorer: An online encyclopedia of life [web application]. Version 7.1. NatureServe, Arlington, Virginia. Available online at: http://explorer.natureserve.org. Date accessed: September 17, 2015; USFWS (U.S. Fish and Wildlife Service). 2013. Endangered Species. October 21. Available online at: http://www.fws.gov/endangered/map/ESA_success_stories/NV/NV_story2/index.html. Date accessed: September 17, 2015.

Vulnerability Factors and Indicator	211—Moapa coriacea	Stressor	Moapa coriacea
All populations at least stable, and one or more increasing populations	Lower	Water diversion	
Small, endemic, constrained, and/or isolated population(s)	Higher	Habitat alteration for recreational use	
Small number of individuals in one or more populations	Higher	Nonnative fish	
Sensitive to stochastic events (natural and/or anthropogenic)	Higher		
Multiple populations (few)	Moderate		
Unknown reproductive rate	Unknown		
Contaminants (including but not limited to pesticides) not specifically mentioned in listing and recovery documents	Unknown		

Rationale Related to Vulnerability

This species is assumed to have moderate vulnerability. While still sensitive to stochastic events and presence much reduced from the past, recent counts have shown increasing trends amidst efforts to control nonnative species.

This species has been extirpated from much of its historical range due to habitat modifications and destruction and introduction of nonnative species such as mollies, gambusia, and tilapia. Populations of the species likely fluctuate, with surveys- (2005 to 2013) showing semiannual total estimates of the species ranging from around 450 to just over 1,700 individuals (all streams/reaches combined). The most recent year counts we obtained (from 2013) showed just over 1,200 individuals in February and just over 1,700 in August. Most of the survey results (i.e., between 2008 and 2012, 9 surveys total) reported estimates ranging from 459 and 713 individuals. (Source: Nevada Fish and Wildlife Office and National USFWS websites)

While the increases during this time period are encouraging, we have not found additional survey counts post-2013 to determine whether the trend continues to be increasing, stable, or if numbers have decreased since then. Much of the habitat modification impacting the species occurred many years ago, and efforts to control/reduce nonnative

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species that compete with or prey on this species are likely to be key in helping to recover the species. Stressors remain, including water withdrawals, nonnative species, and risk of stochastic events.

Environmental Baseline/Cumulative Effects Summary

Flows in the Virgin–Muddy River system were fully appropriated by the early 20th century. During those early years of settlement and as engineering practices improved, portions of the Virgin River main stem and the lower Muddy River became dewatered periodically. The majority of the present day threat to the species in terms of habitat destruction occurred in the late 1800s and early 1900s. Hoover Dam was completed in 1935, creating Lake Mead, which inundated the lower 80 kilometers (50 miles) of the Virgin River and the lower 8 kilometers (5 miles) of the Muddy River. Subsequent stocking of nonnative species (illicit or authorized) in Lake Mead to develop a sport fishery and their unrestricted access to the lower reaches of the Virgin and Muddy Rivers introduced a new threat to the Virgin River fishes. Additional water development projects on tributaries to the Virgin River (Santa Clara, Ash Creek, and Beaver Dam Wash) continued through the latter half of the 1900s, and recent water storage projects have replaced older diversion structures in the upper river and further modified Virgin River hydrology. Reduced base flows are of concern for some populations, and habitat conditions can be exacerbated by severe and persistent drought, which is expected to continue to occur in the future. Other important threats continue with introductions of nonnative species, and eradication is challenging and has not been complete. In some streams, critical and behavioral thermal maxima are exceeded for varying periods of time in most years. We anticipate these effects will continue in the future as both results of the environmental baseline and as a result of cumulative effects. Conservation efforts are also being undertaken, with several efforts identified in the recovery plans. For example, the Virgin River Program coordinates, directs, and funds recovery actions for listed species. Other efforts in the Virgin River Basin include several existing or developing habitat conservation and watershed management plans and partnership, some of which have the potential to benefit these species over the long term.

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Recovery Summary	The Moapa dace has been assigned a recovery priority of 1 because it is the only species within the genus <i>Moapa</i> , there is a high degree of threat to its continued existence, and it has a high potential for recovery.	Applicable Recovery Action	None specifically applicable to the proposed action
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Recovery Info Source	U.S. Fish and Wildlife Service. 1995. Recovery Plan for the Rare Aquatic Species of the Muddy River Ecosystem. Portland, Oregon. 60 pp.; U.S. Fish and Wildlife Service. 1994. Virgin River Fishes Recovery Plan. Salt Lake City, Utah. 45 pp.
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Other Relevant Notes (if any):

"This species has been identified as a key species for the Warm Spring Natural Area, a property acquired by the Southern Nevada Water Authority. A wide array of partners, including the U.S Fish and Wildlife Service, collaborate on management of the 1,220 acre parcel for this and other sensitive species. Their mission is, in part, to "manage the property as a natural area for the benefit of native species and for the recovery of the endangered Moapa Dace..." The Warm Springs Natural Area Stewardship Plan describes the following measures related to the use of pesticides: "The management strategy follows an Integrated Pest Management (IPM) approach to weed control and/or eradication. Mechanical, chemical, and biological control measures will be given due consideration as control treatments. Because of the contamination potential for chemical residues into surface waters supporting Moapa dace and other sensitive aquatic species, non-chemical control options will be given priority in areas where contamination is possible. Chemicals that can directly or indirectly affect fish will not be used within a generous buffer zone, in windy conditions, or during inclement weather. The use of any chemical within or bordering dace habitat will require coordination with the US Fish and Wildlife Service. In all instances, best management practices will apply. Use of any restricted chemical will require an on-site, licensed person for the duration of chemical application. Care will be taken to prevent the bioaccumulation of systemic chemicals in soils or systems caused by multiple applications or by using highly persistent chemicals. The development of an [Integrated Pest Management] Plan for the property would address the various issues associated with managing pest species at the [Warm Springs Natural Area]. Additionally, the plan refers to land cover uses.

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The area is comprised of a number of ecological assemblages. One category is “abandoned agricultural fields”, which implies that these lands are not likely to be managed for agriculture for the foreseeable future. Citation: Southern Nevada Water Authority. 2011. Warm Springs Natural Area Stewardship Plan. Southern Nevada Water Authority,

Summary of Effects of the Proposed Action

Likelihood of Exposure

The Moapa dace occurs in limited reaches of the Muddy River, its tributaries, and headwater thermal springs/pools all within a single HUC12 located in Clark Co. Nevada. The aggregated percent overlap for all uses (not including mosquito control) is 1.3% with individual use sites ranging from 0.02% (wheat) to 0.64% (pasture).

Although pesticide use sites occur in a low percentage of the range they are located near Moapa dace habitat. Therefore, the likelihood of exposure would be greater expected based solely on the low overlap.

Adult dace inhabit the main stem of the Muddy River and migrate upstream to slow-moving thermal spring out flows to spawn. Reproduction occurs year-round with peak spawning activity in the spring. Larval dace are found only in upper reaches of tributaries, and occur most frequently in slack water. Juveniles occur throughout tributaries, and occupy habitats within increasing flow velocities as they grow. One or more life stages will be present throughout the year.

The majority of Moapa dace habitat is located on Moapa Valley National Wildlife Refuge or the Warm Springs Natural Area (WSNA). In both locations conservations plans are in place and focused on habitat restoration and recovery of the Moapa dace.

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"Therefore, the likelihood of exposure would be greater expected based solely on the low overlap."

Risk to individual(s) if exposed

The risk of mortality to individuals would range from 99% in thermal spring out flows (bin 2), 50 – 100% in thermal springs/pools (bin 6), and less than 0.01% in the main stem of the Muddy River (bin 3) for most of the pesticide use sites. Surviving individuals in spring out flows and springs/pools would also be at risk for growth and behavioral effects. Based on the Weight of Evidence from the BE, we have high confidence in this estimate of risk to individuals within a population.

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The risk of mortality to individuals would range from 99% in thermal spring out flows (bin 2), 50 – 100% in thermal springs/pools (bin 6), and less than 0.01% in the main stem of the Muddy River (bin 3) for most of the pesticide use sites.

Does this mean that there is a 99% chance of mortality to an individual in bin 2? Does it mean that 99% of exposed individuals in bin 2 would die?

Mortality Line of Evidence (Mag Tool Output)

Populations in small outflow streams (bin2) and headwater springs/pools (bin6) would experience about 1% mortality each year, on average, while mortality among populations in the main stem of the Muddy River (bin 3) is anticipated to be less than 0.01%.

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Commented [GK14]: This should be focused on impacts to the population, not to individuals.

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Sublethal (MagTool Output)

A low percentage of the population is anticipated to experience adverse effects on growth, reproduction, or behavior as a result of malathion exposure (less than 1% each year on average).

Indirect Effects (MagTool Output)

Effects on prey (aquatic invertebrates) are predicted to be less than 2% (mortality) in small outflow streams (bin2) and headwater springs/pools (bin 6). Higher effects are predicted for the main stem of the Muddy River (bin 3). Sensitive aquatic invertebrate prey would experience around 1% mortality on average but as high as 60% at some point during the 15 year action. Less sensitive prey are not expected to be adversely affected.

Volatilization

We do not expect transport from volatilization to be an appreciable source of exposure for this species.

Dermal

Not Applicable for aquatic species

Mosquito Adulticide (MagTool Output)

The malathion label allows for mosquito adulticide application at any location at a maximum frequency of once a week. While the entire range of the Moapa dace could be exposed to this use, we do not expect that mosquito adulticide usage will be either this expansive or frequent. However, each spray is likely to result in 80% mortality to exposed individuals in small outflow streams (bin 2), 5 – 80% mortality in headwater springs/pools (bin 6), 1 – 45% mortality in the main stem of the Muddy River (bin 3).

Mixtures Line of Evidence

See section General Effects

Abiotic Line of Evidence

See section General Effects

Summary of Rationale for Conclusion

Conclusion (Malathion):

After reviewing the current status of the listed species and designated critical habitat, the environmental baseline for the action area, the effects of the proposed registration of malathion, and the cumulative effects, it is the Service's Biological Opinion that the registration of malathion, as proposed, is not likely to jeopardize the continued existence of the Moapa dace.

Rationale:

Several vulnerability factors for this species suggest a higher vulnerability, such as small, isolated populations, sensitivity to stochastic events, and a relatively small number of individuals in one or more populations. However, numbers are also increasing and most of the individuals are located within the bounds of the Warm Springs Natural Area, which has specific protective measures related to use of pesticides in or near Moapa dace habitat. These measures include generous buffers and coordination with the U.S. Fish and Wildlife Service. The Warm Springs Natural Area's Stewardship Plan is the result of collaboration of multiple land and conservation partners, with a specific focus on managing the area for the recovery of the species. In our preliminary analysis, pesticide use sites seemed likely to occur in a low percentage of the range of the species; upon closer review, the use sites appear to be more concentrated near the species habitat. However, review of the Stewardship Plan suggests that much of the nearby agricultural fields are considered to be abandoned fields. The majority of Moapa dace habitat is located on Moapa Valley National Wildlife Refuge or the Warm Springs Natural Area (WSNA). In both locations conservation plans are in place and focused on habitat restoration and recovery of the Moapa dace.

Where individuals are directly exposed to malathion, we anticipate high levels of mortality in small flowing and static waters, but very low levels in the main stem of the Muddy River. Stepping the effects of the action up to populations, where populations are exposed (based on the outputs of the MagTool), we anticipate very low reductions in survival, growth, and reproduction of individuals within the population ($\leq 1\%$ each year for each line of evidence). We also expect behavioral effects to be similarly low. Indirect effects to prey are also anticipated to be very low, although we acknowledge a large reduction (up to 60%) of prey items that are highly sensitive to the pesticide may occur once over the course of the action. However, we anticipate that other prey items would be available during that time, and that recolonization from upstream areas would avoid any long-term effects of such a reduction.

However, we anticipate that the management of the Warm Springs Natural Area, in coordination with the various partners, including the FWS, would preclude most of these effects to the species. Thus, the anticipated direct and indirect effects of the action, combined with the effects of interrelated and interdependent actions,

Commented [GK16]: This species has no designated critical habitat

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Commented [PA18]: Above it says moderate vulnerability

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Commented [EW21]: This sounds like a good rationale for an early off-ramp. The species' immediate environs are well-protected by responsible institutions.

Commented [GK22]: This overstates the confidence in the risk conclusions. This does not account for alternative assumptions regarding species sensitivities.

and the cumulative effects associated with future state, tribal, local, and private actions will not appreciably reduce Moapa dace survival, numbers, and distribution at the scale of the range of the species.

Critical Habitat Conclusion: Critical habitat has not been designated for this species.

Rationale:

Integration and Synthesis Summary: Fishes

MALATHION - DRAFT

Family	Cyprinidae	Species:	Moapa coriacea	Moapa dace	Entity ID:	211
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Summary of Status, Environmental Baseline, and Cumulative Effects

Species Level Trends	Increasing	Number of Populations	6-20
Population Level Trends	Increasing	Population Size	A population survey in 2013 found 1,727 individuals (USFWS 2013).

Population Narrative	Based on current surveys, trends show an increase in population sizes for the species (USFWS 2013). There are currently between 6 and 20 occurrences-populations (NatureServe 2015), with a total population-numbersize of 1,727 individuals throughout their range (USFWS 2013). The species is moderately resilient, but representation and redundancy are low. Population growth rate appears to be stable. Based on the narrow range of the species, adaptability is low.
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Vulnerability Factors and Indicator	211—Moapa coriacea	Stressor	Moapa coriacea
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Small, endemic, constrained, and/or isolated population(s)	Higher	Habitat alteration for recreational use	
Small number of individuals in one or more populations	Higher	Nonnative fish	
Sensitive to stochastic events (natural and/or anthropogenic)	Higher		
Multiple populations (few)	Moderate		
Unknown reproductive rate	Unknown		
Contaminants (including but not limited to pesticides) not specifically mentioned in listing and recovery documents	Unknown		

Rationale Related to Vulnerability

This species is assumed to have moderate vulnerability. While still sensitive to stochastic events and presence much reduced from the past, recent counts have shown increasing trends amidst efforts to control nonnative species.

This species has been extirpated from much of its historical range due to habitat modifications and destruction and introduction of nonnative species such as mollies, gambusia, and tilapia. Populations of the species likely fluctuate, with surveys- (2005 to 2013) showing semiannual total estimates of the species ranging from around 450 to just over 1,700 individuals (all streams/reaches combined). The most recent year counts we obtained (from 2013) showed just over 1,200 individuals in February and just over 1,700 in August. Most of the survey results (i.e., between 2008 and 2012, 9 surveys total) reported estimates ranging from 459 and 713 individuals. (Source: Nevada Fish and Wildlife Office and National USFWS websites)

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Flows in the Virgin–Muddy River system were fully appropriated by the early 20th century. During those early years of settlement and as engineering practices improved, portions of the Virgin River main stem and the lower Muddy River became dewatered periodically. The majority of the present day threat to the species in terms of habitat destruction occurred in the late 1800s and early 1900s. Hoover Dam was completed in 1935, creating Lake Mead, which inundated the lower 80 kilometers (50 miles) of the Virgin River and the lower 8 kilometers (5 miles) of the Muddy River. Subsequent stocking of nonnative species (illicit or authorized) in Lake Mead to develop a sport fishery and their unrestricted access to the lower reaches of the Virgin and Muddy Rivers introduced a new threat to the Virgin River fishes. Additional water development projects on tributaries to the Virgin River (Santa Clara, Ash Creek, and Beaver Dam Wash) continued through the latter half of the 1900s, and recent water storage projects have replaced older diversion structures in the upper river and further modified Virgin River hydrology. Reduced base flows are of concern for some populations, and habitat conditions can be exacerbated by severe and persistent drought, which is expected to continue to occur in the future. Other important threats continue with introductions of nonnative species, and eradication is challenging and has not been complete. In some streams, critical and behavioral thermal maxima are exceeded for varying periods of time in most years. We anticipate these effects will continue in the future as both results of the environmental baseline and as a result of cumulative effects. Conservation efforts are also being undertaken, with several efforts identified in the recovery plans. For example, the Virgin River Program coordinates, directs, and funds recovery actions for listed species. Other efforts in the Virgin River Basin include several existing or developing habitat conservation and watershed management plans and partnership, some of which have the potential to benefit these species over the long term.

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Mortality Line of Evidence (Mag Tool Output)

Populations in small outflow streams (bin2) and headwater springs/pools (bin6) would experience about 1% mortality each year, on average, while mortality among populations in the main stem of the Muddy River (bin 3) is anticipated to be less than 0.01%.

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Sublethal (MagTool Output)

A low percentage of the population is anticipated to experience adverse effects on growth, reproduction, or behavior as a result of malathion exposure (less than 1% each year on average).

Indirect Effects (MagTool Output)

Effects on prey (aquatic invertebrates) are predicted to be less than 2% (mortality) in small outflow streams (bin2) and headwater springs/pools (bin 6). Higher effects are predicted for the main stem of the Muddy River (bin 3). Sensitive aquatic invertebrate prey would experience around 1% mortality on average but as high as 60% at some point during the 15 year action. Less sensitive prey are not expected to be adversely affected.

Volatilization

We do not expect transport from volatilization to be an appreciable source of exposure for this species.

Dermal

Not Applicable for aquatic species

Mosquito Adulticide (MagTool Output)

The malathion label allows for mosquito adulticide application at any location at a maximum frequency of once a week. While the entire range of the Moapa dace could be exposed to this use, we do not expect that mosquito adulticide usage will be either this expansive or frequent. However, each spray is likely to result in 80% mortality to exposed individuals in small outflow streams (bin 2), 5 – 80% mortality in headwater springs/pools (bin 6), 1 – 45% mortality in the main stem of the Muddy River (bin 3).

Mixtures Line of Evidence

See section General Effects

Abiotic Line of Evidence

See section General Effects

Summary of Rationale for Conclusion

Conclusion (Malathion):

After reviewing the current status of the listed species and designated critical habitat, the environmental baseline for the action area, the effects of the proposed registration of malathion, and the cumulative effects, it is the Service's Biological Opinion that the registration of malathion, as proposed, is not likely to jeopardize the continued existence of the Moapa dace.

Rationale:

Several vulnerability factors for this species suggest a higher vulnerability, such as small, isolated populations, sensitivity to stochastic events, and a relatively small number of individuals in one or more populations. However, numbers are also increasing and most of the individuals are located within the bounds of the Warm Springs Natural Area, which has specific protective measures related to use of pesticides in or near Moapa dace habitat. These measures include generous buffers and coordination with the U.S. Fish and Wildlife Service. The Warm Springs Natural Area's Stewardship Plan is the result of collaboration of multiple land and conservation partners, with a specific focus on managing the area for the recovery of the species. In our preliminary analysis, pesticide use sites seemed likely to occur in a low percentage of the range of the species; upon closer review, the use sites appear to be more concentrated near the species habitat. However, review of the Stewardship Plan suggests that much of the nearby agricultural fields are considered to be abandoned fields. The majority of Moapa dace habitat is located on Moapa Valley National Wildlife Refuge or the Warm Springs Natural Area (WSNA). In both locations conservation plans are in place and focused on habitat restoration and recovery of the Moapa dace.

Where individuals are directly exposed to malathion, we anticipate high levels of mortality in small flowing and static waters, but very low levels in the main stem of the Muddy River. Stepping the effects of the action up to populations, where populations are exposed (based on the outputs of the MagTool), we anticipate very low reductions in survival, growth, and reproduction of individuals within the population ($\leq 1\%$ each year for each line of evidence). We also expect behavioral effects to be similarly low. Indirect effects to prey are also anticipated to be very low, although we acknowledge a large reduction (up to 60%) of prey items that are highly sensitive to the pesticide may occur once over the course of the action. However, we anticipate that other prey items would be available during that time, and that recolonization from upstream areas would avoid any long-term effects of such a reduction.

However, we anticipate that the management of the Warm Springs Natural Area, in coordination with the various partners, including the FWS, would preclude most of these effects to the species. Thus, the anticipated direct and indirect effects of the action, combined with the effects of interrelated and interdependent actions,

Commented [GK16]: This species has no designated critical habitat

Commented [GK17]: Major uncertainties should be incorporated into this section

Commented [PA18]: Above it says moderate vulnerability

Commented [PM19]: What is a 'generous' buffer?

Commented [GK20]: Where is the analysis supporting this statement?

Commented [EW21]: This sounds like a good rationale for an early off-ramp. The species' immediate environs are well-protected by responsible institutions.

Commented [GK22]: This overstates the confidence in the risk conclusions. This does not account for alternative assumptions regarding species sensitivities.

and the cumulative effects associated with future state, tribal, local, and private actions will not appreciably reduce Moapa dace survival, numbers, and distribution at the scale of the range of the species.

Critical Habitat Conclusion: Critical habitat has not been designated for this species.

Rationale:

Draft Interpretation of Mag Tool output for Karner Blue Butterfly/malathion:

Commented [GK1]: This analysis is heavily focused on individual level impacts and does not clearly analyze risks to populations or to the overall species.

What is the effect if an individual is exposed?

Commented [GK2]: This header is inconsistent with the text, which is focused on populations.

Based on modeled scenarios, there is potential for up to 100% mortality ~~to among~~ exposed individuals within a population of Karner Blue Butterflies ~~is expected~~ across all crop types.

Commented [GK3]: This overstates our confidence in the assessment. There are major uncertainties, such as surrogacy, that influence our conclusions. more cautious language should be used.

Based on the Weight of Evidence from the BE, we have high confidence in this estimate of risk to individuals within a population.

Likelihood of exposure

Commented [GK4]: This section does not describe how likely it is that individuals will be exposed and how many may be exposed.

Within the range of the Karner Blue Butterfly (consisting of 37 counties among 7 states), the use categories are mosquito adulticide, pasture, corn, open space developed, developed, wheat, vegetables and ground fruit, other row crops, other grains, orchards and vineyards, Christmas trees, and other crops. The total for percent overlap for all uses (less mosquito adulticide) is approximately 37 % with individual use sites ranging from 0.009% for other row crops to 15.3% for pasture.

Commented [GK5]: Usage data should be included here (percent crop treated)

The Karner Blue is known to frequent roadsides, military bases, and forests in search of the nectar/pollen from a nectar plant during the adult stage and may be more likely to be exposed to pesticide use in these scenarios.

Commented [EW6]: What protections are there on military bases? Are the pesticide uses more or less likely there?

The Karner blue butterfly usually has two generations, and thus two hatches, each year. In April, the first group of caterpillars hatch from eggs that were laid the previous year (overwintered eggs). These individuals mature and lay eggs in June on or near wild lupine plants, which become the second generation of adult butterflies appearing in July. These adults mate and lay eggs that will not hatch until the following spring. Therefore, the Karner Blue butterfly is vulnerable to the effects of malathion throughout its entire lifecycle, especially vulnerable are the larval and adult stages if applications are made from April through July.

Risk to the population

Commented [GK7]: Population or species?

Mortality Line of Evidence – MagTool Output

Populations exposed to malathion on sites of application and exposed via spray drift at the maximum application rates would experience 95% mortality each year.

Commented [GK8]: So, this applies to the assumption that an entire population is exposed? To draw a conclusion of how much mortality could potentially exist in a year, we would need to know the proportion of the population that is exposed, in combination with the magnitude of mortality in exposed individuals.

Indirect effects – MagTool Output

The dietary items for this species include grass-broadleaves (the larval stage of this species consumes only leaves from the host plant, wild lupine, *Lupinus perennis* L. (*Fabaceae*), which it has an obligate relationship) and nectar/pollen from other sources (which this species relies on during the adult stage). Approximately 1/3 of the uses associated with the overlap within the Karner Blue range will cause a decline in growth of plant food sources, impacting the ability of the Karner Blue Butterfly to consume enough food during larval or adult stages.

Commented [GK9]: How much decline in plant biomass is predicted? How is the link between a decline in biomass linked to a decline in food availability?

Mosquito adulticide

The malathion label allows for mosquito adulticide application at any location at a maximum frequency of once a week. While the entire range of Karner Blue Butterfly could be exposed to this use, we do not expect that mosquito adulticide usage will be either this expansive or frequent. However each spray ~~is likely to~~ could potentially result in 100% mortality for exposed individuals.

Commented [EW10]: Are these sprays 100% effective for mosquitoes? Do we know anything about the relative sensitivity of butterflies versus mosquitoes?

Mixtures line of evidence

Exposure to mixtures through formulated products, tank mixes, and environmental mixtures ~~is expected could potentially~~ cause increased toxicity to the Karner Blue Butterfly compared to exposure to the active ingredient alone. In general, the magnitude of that increase is uncertain because the composition of mixtures and concentrations of the degradates in the environment is usually not known.

Abiotic factors line of evidence

The effects to an individual Karner Blue described by other lines of evidence could be greater when accounting for deviations in temperature. There is uncertainty regarding the range of temperatures relevant to individual species that are sufficient to alter toxicity of the chemical, as well as the magnitude of any potential effects.

Commented [GK11]: Why is this focused on individuals? This should be focused on impacts to populations or to the species.

Commented [GK12]: How can the effect be even greater than mortality to an individual?

Critical Habitat

This species does not have critical habitat.

DRAFT

Decision Tree for the Effects of the Action

The purpose for this decision tree methodology is to determine what questions or thought processes to consider as species are analyzed with the MagTool, as well as lines of evidence not included in the MagTool. Additionally, this document will serve as a reference guide for users of the MagTool. The following considerations and decision pathways are to help guide the user to determine the process to analyze a taxonomic group, or specific species, while maintaining consistency and transparency through documentation of the approach. Detailed guidelines on each parameter of interest to consider are included in this document. Justification for decisions by taxonomic group or specific species are provided either here, or in the General Exposure by Taxonomic sections of the Opinion. Detailed instructions for parameterizing the MagTool are also included.

IV. PLANTS

All plant species will be assessed in a slightly modified MagTool that will **batch species by habitat group**. The output for the tool will “flag” certain attributes to allow the user to narrow down specific species within a habitat group that may be more of a concern and warrant further investigation and attention for analysis. If there are one or several species within a group that warrant further attention for one of several factors or “flags” of interest, these species may represent or stand in as representative species for the habitat grouping to make species determinations.

There are several “**flags**” that will be part of the output that will allow the user to decide and determine which species require further attention. These “flags” are plant attributes such as the following: pollinator type, seed dispersal type, elevation, **general plant type (terrestrial/wetland/aquatic)**, **grower type (monocot/dicot; to ascertain direct toxicity)**, listing status (T,E,C,P), **FWS region(s) where found**, **FWS region lead**, etc.

Other aspects of the plant MagTool will differ from the terrestrial or aquatic tools and are outlined below.

INPUTS:

Toxicological information by taxonomic group (documented in General Effects by Taxa sections)

- Document decision points and rationale:
 - o For broad taxonomic inputs - General Exposure by Taxa sections
 - o For species-specific inputs – Plant MagTool output for habitat groups and/or effects analysis

1. What lines of evidence will be carried forward for the analysis? Are there lines of evidence that are not carried forward for an entire taxonomic group?

*Plants – **threshold values if warranted** and indirect effects*

Commented [GK1]: Is this correct?

Commented [GK2]: It is not clear why these specific flags were created. Also, the document does not explain how the flags will be used. In order to understand this method, it is necessary to have a clear explanation of what flags will result in identification of a species that needs “further attention”. It is also unclear what “further attention” entails.

Commented [GK3]: Consider using “habitat”

Commented [GK4]: I am unfamiliar with this term. Consider using a taxonomic descriptor.

Commented [GK5]: How does this influence whether or not a species would require further attention? This does not seem to be relevant to the exposure and risk of a species.

Commented [GK6]: Does this mean that the threshold values for the BEs will be used? If so, those values were established for individuals not for population level impacts. I do not think that the no effect thresholds are appropriate for a population level assessment.

2. For each line of evidence identified, define toxicological inputs by taxonomic group (birds, reptiles, terrestrial amphibians, mammals, terrestrial invertebrates). Identify species within taxonomic groups that will deviate from these parameters and how, and provide documentation.

Plants – threshold values for each plant growth type will be used as well and noted if the value was obtained from a growth study (vegetative vigor) or emergence study (seedling emergence)

Commented [GK7]: Why is this included? It seems like this should be specific to plants (e.g., monocots and dicots).

3. Directions for entering the Toxicological Information:

- i. Go to: "Inputs Tab"
- ii. Go to: "Column K" scroll down column K to taxonomic group of interest
- iii. Set the parameters of interest. This includes toxicity endpoints such as lowest LD50, NOAEC/LOAEC levels for sublethal endpoints. (NOTE: this might already be in the tool)
- iv. Enter notes about what the NOAEC or LOAEC level selected means, if appropriate (i.e. LD50 for juveniles vs adults, reduced litter size, decreased growth, etc.), in the comments/notes section for your tox parameter. These parameter details will be carried over for documentation of each run of the tool.

Exposure information by species

- Use Life History SOS worksheet ~~of species SOS~~ to obtain species-specific information, where available
- Document decision points and rationale, where needed:
 - o Documentation location for broad taxonomic inputs - General Exposure by Taxa sections
 - o Documentation location for species-specific inputs - Plant MagTool output habitat groupings and/or effects analysis

1. Is there information available to inform the distribution of the species? If so, adjust percent population exposed.

Plants - assume uniform distribution

Commented [GK8]: Based on the bullet below, this should be deleted.

Commented [GK9]: Is there any attempt to use the GAP data and match it to habitat info?

2. Select mean or upper bound EECs according to extent of movement during foraging. Use mean EECs for species with moderate to great movement during foraging, and upper bound EECs for species with limited movement.

Plants – mean EECs?

Commented [GK10]: This should be deleted.

Commented [GK11]: There are no mean EECs for plants.

3. Adjust percent overlap, where applicable, based on extent of movement during foraging, and distribution of use sites within

Plants – N/A

4. Set duration of exposure window for sublethal effects.

Plants – N/A

5. Select application rates.

a. Maximum use rates are run automatically and are the basis for the JAM decision.

b. Other use rates may be run to consider the effects of individual crops, estimate effects from minimum rates, etc.

6. Are there areas within the range of particular interest and can they be identified? If so, identify and scrutinize further on map (if time allows) that has been made in Arc Map for that habitat group.

1. Is there knowledge base of the area from field office, personal, or map id? Use this information in the Plant MagTool interpretation write up to justify.
2. Run the model w max application rate. Is there a particular use that drives the results? Is there concern w spray drift for this species? Is there a need to run the min application rate?

Flags:

Review flags for the following information to assess habitat groups and indirect effects:

1. Terrestrial/Aquatic/Wetland?
2. Obligate relationship? Y/N
3. Pollinator type? Specific or general?
4. Seed Disperser Type? Specific or general?
5. Life Cycle type – will species not be exposed to a use because it is not present (eg, dormant, not flowering, annual type life cycle, etc.
6. Effect Level – is there an effect level over which there is concern for a given habitat grouping (ie majority of plants in a given group have very low population numbers)? If so identify level and use as filter?
7. Critical Habitat – Does this species have critical habitat and does it belong to a habitat group that can be analyzed this way? Are there core areas or places within the range that have been identified (field office, recovery plan, 5-year review, etc.) and need further scrutiny?

OUTPUTS

- Use Life History worksheet of species SOS to obtain species-specific information, where available
- Document output:
 - o Habitat Group-specific Plant MagTool output worksheet?
 - o Habitat Group-specific effects analysis write-up

Commented [GK12]: This document leaves out critical information on how these outputs are used to draw conclusions of jeopardy/no jeopardy and habitat mod/no mod. Without those decision criteria, this method cannot be fully evaluated. As is, this method is not transparent or reproducible.

Commented [GK13]: How are indirect effects translated to a population level effect for listed plants?

1. Describe the effect of exposure (eg, for each crop, what is magnitude of effects if an individual is exposed)? Use the "Co-occurrence_use sites" spreadsheet to determine if we have information from species experts regarding is the plant prefers a certain use site.

- a. If the species will not grow in any of the use sites, consider only spray drift EECs.

2. Describe the likelihood of exposure

Commented [GK14]: Elevation would also be relevant here

- a. % overlap (MagTool output)

- b. Life Cycle type - will species not be exposed to a use because it is not present (eg, dormant, not flowering, annual type life cycle; or perennial.

- c. Is the pesticide persistent? Are EECs likely to exceed levels that produce adverse effects for multiple days?

3. Describe the risk to the population for each line of evidence, as aggregated across uses.

- a. What attributes have been flagged? How many are there that appear for a given species within a habitat group?
- b. Is there a particular use(s) that drives the results? If so, look at overlay of important uses and species range. Is the area likely to be utilized by species?

4. Describe routes of exposure and uses that were assessed outside of the MagTool, as applicable:

- a. Cattle ear tag (DZN and CYP)

– Refer to "Cattle ear tag BO analysis" document for species indicated below that may experience effects

- b. Seed treatment (CYP)

– Refer to "Seed treatment and granular bait analysis for BO" for species indicated below that may experience effects

- c. Granular uses (CYP)

- d. Bait (CYP)

– Refer to "Seed treatment and granular bait analysis for BO" for species indicated below that may experience effects

Commented [GK15]: For cattle ear tags, plants were NLAA for diazinon and not of concern for chlorpyrifos. This should not be considered in the BO.

- c. Describe the effect of wide area uses:

- a. Wide area use – CYP – (George will write up half-pager)

- i. Run for a single application. Since overlap is 100%, results will be the same across taxa, except where species-specific endpoints such as LD50's are used

- ii. Describe the potential effects to individuals that may be exposed to an area where a spot treatment has been performed.
 - iii. Describe the manner in which mosquito adulticides can be used according to the label (eg, number and frequency of application). *If this is covered in George's write-up, no need to repeat here?*
 - b. Mosquito adulticide – MAL, CYP (Sara will write up half pager)
 - i. Run for a single application. Since overlap is 100%, results will be the same across taxa, except where species-specific endpoints such as LD50's are used
 - ii. Describe the potential effects to individuals that are exposed to a single application.
 - iii. Describe the manner in which mosquitocides can be used according to the label (eg, number and frequency of application). *If this is covered in Sara's write-up, no need to repeat here?*
- 2. Is the species high in elevation and will volatilization be more of an issue?
- 3. Other lines of evidence
 - a. Mixtures – check with NMFS
 - b. Abiotic factors– check with NMFS

Commented [GK16]: How would this be assessed? There are no exposure estimates and no tox data with which to evaluate potential impacts.

Terrestrial Effects Analysis Framework

Key Questions	Information	Risk Metrics
1. What is the evidence supporting risk to individual fitness? 2. What is the anticipated magnitude of the risk to individuals? 3. What proportion of the population is likely to be affected?	<ul style="list-style-type: none"> Supported lines of evidence from the BE. Anticipated exposures and concentration-response relationships Overlay exposure and species distribution in space and time. Species-specific demographic and life history information when available 	Active Ingredient <ul style="list-style-type: none"> Risk of the population experiencing mortality Risk of the population experiencing reproductive effects Risk of population experiencing effects to growth Risk of population experiencing effects to behavior Other Stressors <ul style="list-style-type: none"> Tank Mixtures/Formulated products adding to toxicity Temperature enhancing toxicity

Commented [GK1]: This framework is missing the links between the information considered for a species and how jeopardy/no jeopardy conclusions are drawn.

Commented [GK2]: It's not clear why mixtures and temperature are the metrics to focus on at the population level. Two of the major stressors facing many terrestrial species are habitat loss and impacts from other species (e.g., invasive species, brown headed cowbirds). Why aren't these stressors addressed here?

The purpose for this framework is to determine what questions or thought processes to consider as species are analyzed with the MagTool, as well as lines of evidence not included in the MagTool. Additionally, this document will serve as a reference guide for users of the MagTool. The following considerations and decision pathways are to help guide the user to determine the process to analyze a taxonomic group, or specific species, while maintaining consistency and transparency through documentation of the approach. Detailed guidelines on each parameter of interest to consider are included in this document. Justification for decisions by taxonomic group or specific species are provided either here, or in sections of the Opinion, as listed below. Detailed instructions for parameterizing the MagTool are also included.

Commented [GK3]: This document should also discuss how the mag tool outputs are interpreted. Key questions include: how are risk conclusions (i.e., jeopardy/no jeopardy and habitat mod/no mod) drawn from the outputs of the model? How is the model used to identify RPAs and RPMs?

INPUTS:

Toxicological information by taxonomic group (documented in General Effects by Taxa sections)

- Document decision points and rationale:
 - o For broad taxonomic inputs - General Exposure by Taxa sections
 - o For species-specific inputs - MagTool output spreadsheet and/or effects analysis
- 1. What lines of evidence will be carried forward for the analysis? Are there lines of evidence that are not carried forward for an entire taxonomic group?
 - a. *Birds, Reptiles, Terrestrial Amphibians – mortality, growth, reproduction, and behavior carried forward (no sensory)*

- b. *Mammals – mortality, growth, reproduction, and behavior carried forward (no sensory)*
 - c. *Terrestrial Inverts – mortality only carried forward*
- 2. For each line of evidence identified, define toxicological inputs by taxonomic group (birds, reptiles, terrestrial amphibians, mammals, terrestrial inverts). Identify species within taxonomic groups that will deviate from these parameters and how, and provide documentation.
 - a. *Birds, Reptiles, Terrestrial Amphibians –*
 - i. *Mortality: Run avian HC05 and HC50 run for all taxa/species. Also run species specific information where available: Masked bobwhite for all chemicals, Mississippi sandhill crane for CYP only.*
 - 1. **MagTool Instructions for Mortality:**
 - a. **Go to: “Inputs Tab”**
 - b. **Go to: “Column K” scroll down column K to section for taxonomic group and endpoint**
 - c. **Section Locations for Birds**
 - i. **cell “K76” (dose based)**
 - ii. **cell “K106” (dietary based)**
 - d. **Section Locations for Reptiles**
 - i. **cell “K85” (dose based)**
 - ii. **cell “K119” (dietary based)**
 - e. **Amphibians – cell “”**
 - ii. *Sublethal: For all taxa/species, run MagTool with endpoints as described in General Effects by Taxa section for all taxa. Consider bobwhite quail data for Masked bobwhite where available, and different then standard endpoints.*
 - 1. **MagTool Instructions for Sublethal:**
 - a. **Go to: “Inputs Tab”**
 - b. **Go to: “Column K” scroll down column K to taxonomic group of interest**
 - c. **Sublethal section locations for Birds**
 - i. **Growth - cell “O106”**
 - ii. **Reproduction – cell “R106”**
 - iii. **Behavioral – cell “U106”**
 - iv. **Sensory – cell “X106”**
 - d. **Sublethal section locations for Reptiles**
 - i. **Growth - cell “K119”**
 - ii. **Reproduction – cell “O119”**
 - iii. **Behavioral – cell “U119”**
 - iv. **Sensory – cell “X119”**
 - e. **Sublethal section locations for Amphibians**
 - i. **cell “”**
 - 2. **Set the parameters of interest. This includes toxicity endpoints such as lowest LD50, NOAEC/LOAEC levels for sublethal endpoints. (NOTE: this might already be in the tool)**
 - 3. **Enter notes about what the NOAEC or LOAEC level selected means, if appropriate (i.e. LD50 for juveniles vs adults, reduced litter size, decreased growth, etc.), in the comments/notes section for your tox parameter. These notes will be carried over for documentation in each run of the tool.**

b. **Mammals –**

i. *Mortality: Run lowest LD50 and LC50 run for all species.*

1. **MagTool Instructions for Mortality:**

- a. *Go to: “Inputs Tab”*
- b. *Go to: “Column K” scroll down column K to section for taxonomic group and endpoint*
- c. *Section Locations for Mammals*
 - i. *cell “K69” (dose based)*
 - ii. *cell “K93” (dietary based)*

2. *Set the parameters of interest. This includes toxicity endpoints such as lowest LD50, NOAEC/LOAEC levels for sublethal endpoints. (NOTE: this might already be in the tool)*

3. *Enter notes about what the NOAEC or LOAEC level selected means, if appropriate (i.e. LD50 for juveniles vs adults, reduced litter size, decreased growth, etc.), in the comments/notes section for your tox parameter. These notes will be carried over for documentation in each run of the tool.*

ii. *Sublethal: For all species, run MagTool with endpoints as described in General Effects by Taxa section for all taxa.*

1. **MagTool Instructions for Sublethal:**

- a. *Go to: “Inputs Tab”*
- b. *Go to: “Column K” scroll down column K to taxonomic group of interest*
- c. *Sublethal section locations for Mammals*
 - i. *Growth - cell “O93”*
 - ii. *Reproduction – cell “R93”*
 - iii. *Behavioral – cell “U93”*
 - iv. *Sensory – cell “X93”*

2. *Set the parameters of interest. This includes toxicity endpoints such as lowest LD50, NOAEC/LOAEC levels for sublethal endpoints. (NOTE: this might already be in the tool)*

3. *Enter notes about what the NOAEC or LOAEC level selected means, if appropriate (i.e. LD50 for juveniles vs adults, reduced litter size, decreased growth, etc.), in the comments/notes section for your tox parameter. These notes will be carried over for documentation in each run of the tool.*

c. **Terrestrial Inverts –**

i. *Mortality: Run lowest LD50 or LC50 for all chemicals for all species except for Chlorpyrifos Diptera, the lowest LC50 value for this Order will be used to address effects for this Order only for this chemical.*

ii. **MagTool Instructions for Mortality::**

1. *Go to: “Inputs Tab”*
2. *Go to: “Column K” scroll down column K to taxonomic group of interest*
3. *Section locations for Terrestrial Inverts*
 - a. *cell “K137 (dose based)*
 - b. *cell “K144” (dietary based)*

4. *Set the parameters of interest. This includes toxicity endpoints such as lowest LD50, NOAEC/LOAEC levels for sublethal endpoints. (NOTE: this might already be in the tool)*
 5. *Enter notes about what the NOAEC or LOAEC level selected means, if appropriate (i.e. LD50 for juveniles vs adults, reduced litter size, decreased growth, etc.), in the comments/notes section for your tox parameter. These notes will be carried over for documentation in each run of the tool.*
- iii. **MagTool Instructions for Sublethal:**
1. *Go to: "Inputs Tab"*
 2. *Go to: "Column K" scroll down column K to taxonomic group of interest*
 3. *Sublethal section locations for Terrestrial Inverts*
 - a. *Growth - cell "K154"*
 - b. *Reproduction – cell "K159"*
 - c. *Behavioral – cell "KK164"*
 - d. *Sensory – cell "LK169"*
 4. *Set the parameters of interest. This includes toxicity endpoints such as lowest LD50, NOAEC/LOAEC levels for sublethal endpoints. (NOTE: this might already be in the tool)*
 5. *Enter notes about what the NOAEC or LOAEC level selected means, if appropriate (i.e. LD50 for juveniles vs adults, reduced litter size, decreased growth, etc.), in the comments/notes section for your tox parameter. These notes will be carried over for documentation in each run of the tool.*
3. Define toxicological inputs for indirect effects on dietary items using endpoints from the input table for Step 2.
- a. For obligates, run the HC05 or lowest LC50/LD50 for the prey taxa.
 - b. For other species, run the HC05 and HC50 for prey taxa with SSDs and the lowest LC50/LD50 for prey taxa with no SSDs.
 - c. For Terrestrial invertebrates = for obligates, the tool will run the NOAEC/LOAEC for growth for the dietary item (plant threshold value)
 - d. For plants (shelter/cover):
 - e. **MagTool Instructions for Indirect Effects:**
 - i. *Go to: "Inputs Tab"*
 - ii. *Go to: "Column K" scroll down column K to taxonomic group of interest*
 - iii. *Go to: cell "K221"*

Exposure information by species

- Use Life History worksheet of species SOS to obtain species-specific information, where available
- Document decision points and rationale, where needed:
 - o Documentation location for broad taxonomic inputs - General Exposure by Taxa sections
 - o Documentation location for species-specific inputs - MagTool output spreadsheet and/or effects analysis

1. MagTool Directions for selecting a species:

Commented [GK4]: In order to evaluate this method, more information is needed on the nature of these decision points.

- a. **Go to: "Step 3 Animal Tab"**
 - i. **Go to cell: "C4" and adjust the species of interest by typing in the entityID**
2. For CYP and MAL, set "percent population exposed" to zero for wide area use and mosquito adulticide. These uses will be analyzed separately.
3. Is there information available to inform the distribution of the species? If so, adjust percent population exposed.
 - a. *Birds, Reptiles, Terrestrial Amphibians* – assume uniform distribution except where species specific information exists
 - b. *Mammals* – assume uniform distribution except where species specific information exists
 - c. *Terrestrial Inverts* – assume uniform distribution
 - d. **MagTool Instructions**
 - i. **Go to: "Step 3 Animal Tab"**
 - ii. **Go to cell: "Q10" – the column under this cell allows for adjustment of percent population exposed by use.**
 - iii. **Go to: cell "Q11" – ensure that this use is set at zero (mosquito adulticide)**
 - iv. **Go to: cell "Q12" – ensure that this use is set at zero (wide area use)**
 - v. **If species specific information exists, adjust the percent population exposed under cell "Q10" by use.**
4. Select mean or upper bound EECs according to extent of movement during foraging. Use mean EECs for species with moderate to great movement during foraging, and upper bound EECs for species with limited movement.
 - a. *Birds, Reptiles, Terrestrial Amphibians* – generally mean EECs, with species specific deviations (eg, condors feed on a single carcass per event)
 - b. *Mammals* – mean EECs, with species specific deviations
 - c. *Terrestrial Inverts* – upper bound EECs are the default
 - d. **MagTool Instructions**
 - i. **Go to: "Step 3 Animal Tab"**
 - ii. **Go to cell: "C7" - to adjust the "mean" or "upper bound" in the pull-down menu to adjust EECs values**
5. Adjust percent overlap, where applicable, based on extent of movement during foraging, and distribution of use sites within
 - a. *Birds, Reptiles, Terrestrial Amphibians* – increase percent overlap for birds that forage over a large distance (eg, condor, wood stork)
 - b. *Mammals* – increase percent overlap for mammals that forage over a large distance
 - c. *Terrestrial Inverts* – N/A
 - d. **MagTool Instructions**
 - i. **Go to: "Step 3 Animal Tab"**
 - ii. **Go to cell: "R10"**
6. Set duration of exposure window for sublethal effects.
 - a. *Birds, Reptiles, Terrestrial Amphibians* – 1 day
 - b. *Mammals* – 1 day
 - c. *Terrestrial Inverts* – N/A
 - d. **MagTool Instructions**

Commented [GK5]: What are the nature of these data? How is the population exposed adjusted?

Commented [GK6]: When considering impacts to individuals receiving exposures at the high end of the distribution of exposures, this is appropriate. The use of upper bound EECs is not appropriate when assessing exposure and resulting effects to the population. The mean is the appropriate EEC.

Commented [GK7]: I see no adjustments for percent crop treated. For wide ranging species, it is not reasonable to assume that 100% of potential use sites are actually treated. The SLUAs from the BEs and the refined usage analysis for diazinon should be incorporated to estimate more reasonable measures of the percent of the population exposed.

- i. Go to: "Step 3 Animal Tab"*
- ii. Go to cell: "C8" and select duration of exposure window (set to 1 day for most cases for terrestrial)*

7. Select application rates.
 - a. Maximum use rates are run automatically and are the basis for the JAM decision.*
 - b. Other use rates may be run to consider the effects of individual crops, estimate effects from minimum rates, etc.*
 - c. MagTool Instructions**
 - i. Go to: "CLD Use Rates" tab for minimum maximum single rates to use to adjust in the "Step 3 Animal Tab" described below.*
 - ii. Go to: "Step 3 Animal Tab"*
 - iii. Go to cell: "G10" - the column under this cell allows for adjustment of the application rates by use. The default is set at maximum and is the basis for the JAM decision.*

OUTPUTS

- Use Life History worksheet of species SOS to obtain species-specific information, where available
 - Document output:
 - o Species-specific MagTool output worksheet
 - o Species-specific effects analysis write-up
1. Describe the effect of exposure (eg, for each crop, what is magnitude of mortality/sublethal effects if an individual is exposed)?
 - a. Use the "Co-occurrence_use sites" spreadsheet to determine if we have information from species experts regarding individuals entering the use sites.
 - i. If the species will forage or breed on the use site, consider primarily EECs from on-site exposure.
 - ii. If the species passes through the use site only, consider dermal EECs from on-site exposure, and spray drift EECs for off-site exposure.
 - iii. If the species will not enter use site, consider only spray drift EECs.
 - iv. If no information is available, assume that the species will enter the use site.
 - b. What is the confidence in these estimates? Carry forward the confidence determination for each line of evidence from the BE WOE matrix.
 2. Describe the likelihood of exposure
 - a. What percentage of the species range is anticipated to have pesticide use sites? Which use categories have the greatest overlap? [Were MagTool inputs adjusted to account for this factor]
 - b. Seasonality – will species avoid exposure for part of the year (eg, migration, hibernation, estivation)? If so, are there important life stages (eg, breeding) not subject to exposure?
 - c. Number of applications. Are multiple applications authorized?
 - d. Is the pesticide persistent? Are EECs likely to exceed levels that produce adverse effects for multiple days?

- e. Proximity of use sites to species habitat and sensitive areas. If a species is known to move within their range, on a daily basis or during migration, what does that mean in terms of their likelihood of exposure or the magnitude of exposure-effect compared to what would be anticipated based on the mag tool output. [Were MagTool inputs adjusted to account for this factor]
 - f. Spray drift. How will the likelihood of exposure (or the percent of the population exposed) be affected if areas within the species range that receive spray drift are included in the percent overlap?
 - g. Based on the above factors will we 1) have a better understanding of the likelihood of exposure 2) know whether there will be more or less risk than is predicted by the MagTool and 3) know whether we have higher or lower confidence in our ability to assess proportion of the population that will be exposed and the resulting risk to the population. [General discussion of these factors for taxonomic groups will be covered in the General Exposure Characterization section]
3. Describe the risk to the population for each line of evidence, as aggregated across uses.
 - a. Consider both dose-based and dietary outputs for mortality. Consider toxicological data that were available to parameterize the input values as well as the circumstances of probable exposure (eg, grazing over course of day vs ingestion of bolus)
 - b. Are one or more dietary items driving the effects? If so, do we have information about dietary preference for this species?
 - c. Is there a particular use(s) that drives the results? If so, look at overlay of important uses and species range. Is the area likely to be utilized by species? If so, is there information as to how densely it will be occupied (eg, is it an important breeding or roosting site). Adjust percent population exposed where applicable.
 4. Describe routes of exposure and uses that were assessed outside of the MagTool, as applicable:
 - a. Dermal exposure – consider the likelihood of exposure via this route for each species.
 - o For direct spray, are individuals likely to be on the use site at the time of application? If so, will they be subject to direct spray or will it be intercepted by canopy or other cover?
 - o For contact with contaminated media (assessed for birds and mammals only), are individuals likely to be on the use site or spray drift area? Are they likely to contact the targeted sites of application (eg, canopy for forest spray)?
 - o cursory analysis for species likely to experience significant effects from dietary routes, and more in-depth analysis of likelihood and risk of exposure for other species.
 - i. *Birds (based on dermal dose – contact (mean)) , Reptiles and Terrestrial Amphibians (based on dermal dose – spray) –*
 - CYP – all individuals may experience mortality from dermal exposure alone (with the exception of large reptiles: American crocodile, gopher tortoise, sonoran tortoise)
 - DZN – all individuals may experience mortality from dermal exposure alone

Commented [GK8]: How is "likelihood of exposure" characterized? Is this "low", "medium" or "high"? If so, explicit criteria for each category should be defined.

Commented [GK9]: How?

- MAL – magnitude of mortality and potential to experience sublethal effects varies by body weight, see Dermal Exposure doc
 - ii. *Mammals (based on dermal dose – contact (mean)) –*
 - CYP – all individuals may experience mortality from dermal exposure alone
 - DZN – magnitude of mortality 0.3 - 10% from dermal exposure alone, potential for sublethal effects for all species
 - MAL – no mortality expected from dermal effects alone, potential for sublethal effects for all species
 - iii. *Terrestrial Inverts*
 - *already assessed by MagTool for all chemicals*
- b. Volatilization/Atmospheric transport
- i. *Birds, Reptiles, Terrestrial Amphibians –*
 - ii. *Mammals –*
 - iii. *Terrestrial Inverts -*
- c. Cattle ear tag (DZN and CYP): Refer to “Cattle ear tag BO analysis” document for species indicated below that may experience effects
- i. *Birds, Reptiles, Terrestrial Amphibians*
 - *Carrion eaters*
 - *Insectivorous species*
 - ii. *Mammals*
 - *Carrion eaters*
 - *Insectivorous species*
 - iii. *Terrestrial Inverts*
 - *Insectivorous species only*
- d. Seed treatment (CYP): On-site exposure only (ie, no off-site transport); refer to “Seed treatment and granular bait analysis for BO” for species indicated below that may experience effects
- i. *Birds, Reptiles, Terrestrial Amphibians*
 - *Granivorous and omnivorous species only*
 - ii. *Mammals*
 - *Granivorous and omnivorous species only*
 - iii. *Terrestrial Inverts –*
 - *Granivorous and omnivorous species only; mortality if exposed*
- e. Granular uses (CYP) : On-site exposure only (ie, no off-site transport); refer to “Seed treatment and granular bait analysis for BO” for species indicated below that may experience effects
- i. *Birds, Reptiles, Terrestrial Amphibians*
 - *grainivorous, frugivorous, and insectivorous birds only; exposure to all other species/taxa is not anticipated*
 - ii. *Mammals*
 - *exposure is not anticipated*
 - iii. *Terrestrial Inverts*
 - *Insects that contact contaminated soil or ingest plants that uptake CYP from soil; mortality*

f. Bait (CYP): On-site exposure only (ie, no off-site transport); refer to “Seed treatment and granular bait analysis for BO” for species indicated below that may experience effects

- i. *Birds, Reptiles, Terrestrial Amphibians*
 - *All species may be exposed*
- ii. *Mammals*
 - *All species may be exposed*
- iii. *Terrestrial Inverts*
 - *Any insect that would ingest bait on ground; mortality*

5. Describe the effect of wide area uses:

a. Wide area use – CYP

- i. Run for a single application. Since overlap is 100%, results will be the same across taxa, except where species-specific endpoints such as LD50's are used
- ii. Describe the potential effects to individuals that may be exposed to an area where a spot treatment has been performed.
- iii. Describe the manner in which chlorpyrifos can be used according to the label for this use (eg, number and frequency of application).

b. Mosquito adulticide – MAL, CYP

- i. Run for a single application. Since overlap is 100%, results will be the same across taxa, except where species-specific endpoints such as LD50's are used
- ii. Describe the potential effects to individuals that are exposed to a single application.
- iii. Describe the manner in which mosquito adulticides can be used according to the label (eg, number and frequency of application).

6. Other lines of evidence

- a. Mixtures – coordinate with NMFS
- b. Abiotic factors– coordinate with NMFS

7. Describe indirect effects as output from the MagTool.

The following sections (7a and 7b) describe the impacts to the indirect components of interest to listed species. For example, the MagTool can describe the magnitude of mortality of dietary items (arthropods) as prey base for a listed species of bat. The MagTool can also provide information on the impacts to plants that might be used as habitat for a listed species.

- a. Effects for impacted indirect taxa (e.g. animals as dietary items, pollinators)
 - i. Describe the % effect for toxicological endpoint of interest to the impacted indirect taxa.
- b. Effects for impacted indirect plant species:
 - i. The Magtool output describes how many application rates that overlap with the species range exceed the toxicological endpoint of interest for plants.

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Subject: ESA check-in
Attachments: [ESA STAKEHOLDER WORKSHOP \(Charge Questions WOE Groups\) 6 15 16.docx](#)
[ESA STAKEHOLDER WORKSHOP \(Charge Questions REFINEMENTS\) 6 9 16.docx](#)
[stakeholder wksp breakout sessions w charge questions 061416.docx](#)

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Agenda:

- * ESA stakeholder workshop
- * Agreement on charge questions!

- * Draft BE comment period close

- * BiOp schedule
- * EPA sending exposure values to NMFS/FWS during the summer
- * How goes it with comments on the draft BiOp timeline?

- * Report to Congress

- * - Future BiOp planning group - What is the deadline for the list, can we prioritize neonicotinoids, pyrethroids, and cholinesterase inhibitors on the list, and can we put the development of a programmatic consultations as the goal for out year planning

- * - Where are we with the RPA alternatives for the most recently signed BiOp?

- * - Planning for the meetings on June 27 - 28, 2016 - it is underway!

- * - Who is attending the workshop from NMFS.

ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016):

Breakout Sessions WOE 1 and WOE 2: Weight of Evidence for Listed Animals and Plants

The draft biological evaluations for chlorpyrifos, diazinon and malathion rely upon a weight of evidence (WoE) approach to make species-specific effects determinations. Risk conclusions are based on the integration of exposure and effects information relevant to an individual of a listed species, as well as life history characteristics that may influence exposure or indirect effects (e.g., diet). Different types of effects are identified in this approach as separate lines of evidence; including: mortality, growth, reproduction, behavior, sensory effects and indirect effects. Additionally, other factors that could affect the magnitude of both direct and indirect effects (e.g., chemical or abiotic stressors) are evaluated as lines of evidence. Weighting is applied to each line of evidence and the weighting criteria provide guidelines for supporting effects determinations based on the pairings of risk and confidence. The current weighting criteria are defined in Attachment 1-9.

An effort was made to incorporate and evaluate as much toxicity and exposure data as possible to determine whether adverse effects are anticipated from the effects of the action. Both the toxicity and exposure information are evaluated to determine the risk and confidence associated with each line of evidence. Currently, the process uses numeric thresholds to determine risk. EPA and the services have discussed integrating distributions of effects and exposures to move towards a more probabilistic approach (e.g., such as the method used in the Terrestrial Investigation Model); however, this is seen as more of a long term goal for application to all species. EPA and the Services are interested in suggestions that improve the WoE method. When addressing the questions below, answers will be grouped into “short term” or “long term” solutions, considering the magnitude of work associated with developing and applying the methods to all listed species (n ≈ 1800).

The same set of questions will be considered by the WoE groups focused on plants and on animals; however, the discussions are expected to differ. For instance, issues related to exposure differ between animals and plants in that the routes and models are conceptually and mathematically different. For effects, data are available for multiple lines of evidence for assessing direct effects to animals (i.e., mortality, growth, reproduction, behavior and sensory); whereas mortality, growth and reproduction data are only available for plants. It is expected that discussions related to animals will likely surround the topics of assessing direct effects to listed individuals as well as indirect effects due to impacts on animals and plants. For plants, discussions should probably focus more on indirect effects due to impacts to animals upon which they depend (e.g., for pollination or seed dispersal).

- **Exposure Information-** Criteria used to assess exposure estimates ultimately answer the question, “how confident are we that exposure estimates represent environmental concentrations that could occur based on allowable labeled use?” The current approach for characterizing exposure considers the relevance of predicted EECs for species’ habitats and the robustness of EECs derived from environmental fate models (see Attachment 1-9 for more details). Considering the current approach to characterizing exposure:
 - **CHARGE QUESTION 1:** Comment on/suggest alternative methods for presenting exposure information (e.g., probability distributions, consideration of a range of exposure estimates, consideration of duration of exposure) and how the information can be weighed for each line of evidence’s risk conclusion.
 - **CHARGE QUESTION 2:** Comment on the criteria used to weight Confidence in the estimation of exposure as described in Supplemental Information to Attachment 1-9.

- **Effects Information**- Similar to the exposure characterization, the effects data are evaluated to answer the question, “how confident are we that available toxicity data will accurately predict an effect to the listed species?” The current approach considers 1) biological relevance- whether there is an established relationship between the measure of effect and the assessment endpoint, 2) relevance of surrogate- how representative the tested organisms used in the toxicity studies are at informing the potential for adverse effects to listed species or critical habitat, and 3) robustness- whether there is consistency within the line of evidence for the taxonomic grouping of interest (see Attachment 1-9 for more details). Considering the current approach to characterizing effects:
 - **CHARGE QUESTION 3:** Comment on approaches for incorporating data quality into the weight assigned to a line of evidence. The current approach to data quality is described in Attachment 1-8.
 - **CHARGE QUESTION 4a:** For animals, to what extent can taxa with robust data sets be used as surrogates for other taxonomic groupings where lines of evidence have little or no data (*e.g.*, mammals for reptiles)?
 - **CHARGE QUESTION 4b:** For plants, comment on the approach to surrogacy. Is there a better or more representative way to group species?
 - **CHARGE QUESTION 5:** How can we more effectively incorporate the breadth of the available toxicity information (*i.e.*, not just the most sensitive endpoints), including magnitude of effect, into the characterization of effects and weight of evidence?
 - **CHARGE QUESTION 6:** How can we effectively weigh the impacts of other stressors (*e.g.*, temperature) on the LAA/NLAA call, especially in the event of little or no data?
 - **CHARGE QUESTION 7:** Are there additional sublethal effects that have an established relationship with an assessment endpoint that should be considered as lines of evidence?
 - **CHARGE QUESTION 8:** Comment on the criteria used to weight Confidence in the estimation of effects as described in Supplemental Information to Attachment 1-9.

- **Risk Estimation**- Risk is established by comparing the overlap of exposure with effect levels from available toxicity studies for each line of evidence. Consideration is given to the degree of overlap between exposure and effects data. Considering the current approach to estimating risk:
 - **CHARGE QUESTION 9:** Comment on the criteria used to weight Risk as described in Supplemental Information to Attachment 1-9.

ESA STAKEHOLDER WORKSHOP (JUNE 29 – 30, 2016):

Breakout Session: Refinements to Steps 1 and 2 (Ideas for ‘streamlining’ and/or improving the analyses used to make effects determinations in future BEs)

In accordance with the Endangered Species Act (ESA), the Biological Evaluation (BE) determines whether there is a potential for a single individual of a listed species, or its designated critical habitat, to be adversely affected (directly or indirectly) by a federal agency’s proposed action (in this case registering pesticide labels). This is accomplished by first identifying which species ranges/critical habitats overlap with the ‘action area’¹ (from the BE Step 1: ‘May Affect’/‘No Effect’ determinations). Once a determination is made for each listed species and critical habitat, species- and critical habitat-specific analyses for all listed resources that have ‘May Affect’ determinations are conducted to evaluate whether there is a potential for a single individual (or essential critical habitat feature) to be adversely affected² by the use of a pesticide (BE Step 2: ‘Likely to Adversely Affect’/‘Not Likely to Adversely Affect’ determinations). Therefore, Step 1 is intended to identify those species/critical habitats that require species-specific analyses (*i.e.*, those that need to proceed to Step 2) and Step 2 is intended to identify the potential for adversely affecting a single individual or critical habitat feature. Key to these processes is the ability to identify areas of overlap among potential use sites, areas of potential effects, and species range/critical habitat areas over the duration of the proposed action (in some cases this may be 15 years or more).

- **Breakout Group: REFINEMENTS 1 (Refinements to Steps 1 and 2: Spatial analysis):**

- o For agricultural uses, the interim process identifies potential use sites by collapsing >100 Cropland Data Layer (CDL) classes into 11 agricultural use categories, some of which are unambiguous major crops (corn, cotton, *etc.*), and some of which are aggregated “minor” crops, *e.g.*, orchards and vineyards, or ground fruit and vegetables. (These minor crops were aggregated to address uncertainties in crop identification in the CDL, and to anticipate future use areas for pesticides, based on current uses.) Therefore, in some cases, specific crop uses are being identified in areas where the specific crop likely does not occur. For example, the orchard-vineyard layer is used for all orchard crops, including citrus. Diazinon is registered for some orchard crops, but not citrus – the spatial analysis is showing orchard use sites for diazinon in Florida – but most of those use sites are likely citrus.

¹ The action area is defined by statute as all areas to be affected directly or indirectly by the Federal Action and not merely the immediate area involved in the Action (50 CFR 402.02). The action area is, thus, related to the proposed action and is independent of the geographic area in which listed resources occur.

² Adverse effects to an individual are not limited to mortality, and include short-term and temporary effects (from direct and/or indirect effects) to individuals. Step 2 analyses do not evaluate the potential for “jeopardy” or “adverse destruction/modification” for species and critical habitat, respectively. Such an analysis would be conducted in Step 3 in a Biological Opinion.

- **CHARGE QUESTION 1a: Is there a better way to accurately identify potential agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?**
 - Are there some CDL classes that we have more confidence in than others?
 - Is using the Census of Agriculture to eliminate counties where labeled uses do not occur a viable option for both current uses and future uses (within the duration of the proposed action)? If so,
 - How should we deal with “undisclosed” census values?
 - Do these data (or other suitable data) reflect “no usage” or “low” levels of usage over the duration of the proposed action?
- Non-agricultural label uses include a wide range of land cover and land use categories. In the BEs, each label use is considered and represented by the best available land cover data. Generally, the National Land Cover Dataset (NLCD) is used to represent non-agricultural label uses. When the NLCD is inadequate, other data sources are used as appropriate.
- **CHARGE QUESTION 2a: Is there a better way to accurately identify potential non-agricultural use sites, while still addressing concerns for future use for the duration of the proposed action?**
 - Are there additional data not considered in the BEs that may be useful for geographically identifying non-agricultural use sites?
 - Are there surrogate data (those that could be used to help inform potential use sites) that could be used for non-ag categories that we have not considered?
- Some uses do not have clear geographic boundaries (*i.e.*, they are difficult to limit geographically via label language). For some chemicals, this can result in an action area that encompasses the entire US and its territories.
- **CHARGE QUESTION 3a: How can we better identify potential use sites for pesticide uses that do not have clear geographic boundaries? How could these potential use sites be better identified spatially?**
 - Could a process to modify labels (to clarify potential use sites) be developed during the BE process? If so, what would that process look like?
 - For example, when in the BE process would label clarifications be most useful? Could label modifications be in the form of a registrant commitment to modify a label as part of the final decision? How could Bulletins Live Two be best used in the process?

- For uses such as mosquito adulticide use, what other information could be pulled in to the analyses to help accurately limit the spatial extent (for example census information, or protected/managed lands) for the duration of the proposed action? Is there a human population density threshold where the cost of applying a pesticide would be too high?
 - If it is not possible to geographically define a use site, can we geographically define where the pesticide isn't (or won't be) applied that would provide spatial refinement (*i.e.*, it will not be applied to open water, or urban areas, *etc.*).
- The range data currently available for listed species are geospatially represented using polygons and they are used in the BEs with the assumption that the species use all areas of their polygon equally throughout the year.
 - **CHARGE QUESTION 4a: Are there methods available that would allow for a refined understanding of the distribution of individuals within the range polygons?**
 - Are there methods that can be used to help identify areas of concern within a species' range to better estimate the likelihood of exposure – preferred habitat, distribution of individuals (do they cluster, are they territorial, min patches requirements for a home range, fragmentation indices)?
 - Is there biological information that could be used to help identify areas of the range where exposure is unlikely (*e.g.*, due to elevation restrictions) or very likely (*e.g.*, preferred habitat)?
 - How can the effects on timing be better captured (considering both direct and indirect effects)? For example, for direct effects, at the time of year when a pesticide can be applied, is the species there at that time (*e.g.*, is it only there for part of the year because it is migratory?) or at a life-stage when exposure is or is not likely (*e.g.*, is it at an egg stage, subterranean, or in diapause at that time)? What about the resources it depends on (indirect effects)?
 - Should less refined species ranges (*e.g.*, county-level) be treated differently than those that are more refined [keeping in mind that in many cases a species range is not at a sub-county level for various reasons (*e.g.*, no survey data on private lands, wide-ranging species)]? Is the precision of the analysis equal?
 - Can we incorporate this information to apply a weighting to the overlap analysis (see charge question 5a below)?
- In the pilot BEs, any overlap of the action area with a species range or critical habitat is considered a 'May Affect'.

- **CHARGE QUESTION 5a: Does the overlap approach used in the pilot BEs to determine a 'May Affect/No Effect' determination provide an adequate screening process (one that is protective but not unrealistically conservative)?**
 - When conducting a GIS overlap analysis using datasets with different levels of resolution, what are methods that could be used to ensure that decisions are made based on the datasets' limits of precision (*e.g.*, how can we best avoid 'false positives' and 'false negatives' in the overlap analyses when considering the limits of precision of the datasets used)?
 - Would using a weighting approach for the likelihood of an overlap be useful when making the Step 1 determinations (instead of using only an overlap of the species range/critical habitat and the action area)? For example, for agriculture uses could we incorporate the number of years a cell was classified as the crop in a weighting approach (while still accounting for the duration of the action)?
 - Are there approaches that could be used to screen out species from further analyses besides solely an overlap of the species range/critical habitat and the action area (*e.g.*, if no Step 1 thresholds for plants are exceeded, can plants that are not biologically pollinated be considered 'No Effect', if no other indirect effects are anticipated)?
- **Breakout Group: REFINEMENTS 2 (Refinements to Steps 1 and 2: Non-spatial analysis):**
 - There are a multitude of use patterns on currently registered labels, some which result in potentially higher exposures to non-target organisms than others. For example, although somewhat dependent on chemical fate properties, pesticides applied to large agricultural fields by air are expected to result in higher offsite exposure than pesticides applied to a small area via a ready-to-use spray can.
 - **CHARGE QUESTION 1b: Is there a way to identify use patterns that would result in minimal exposures, such as spot treatments, that may not always need to be fully re-assessed for each pesticide going through the consultation process (*i.e.*, by applying what we have learned from an analysis with another pesticide with a similar use pattern)?**
 - What type of things regarding the pesticide and use site would need to be considered [*e.g.*, the fate properties of the pesticide, the amount of pesticide applied (*e.g.*, per the label and/or based on usage information), the application method used, potential application sites (*e.g.*, ready-to-use spray can)]?
 - Of these fate properties, how could they be considered - keeping in mind use site parameters?
 - Of these use site parameters, how could they be considered (*e.g.*, personal ready-to-use spray can for mosquitos)?

- There are a subset of listed species that are found in places or environments not expected to result in appreciable exposure to most pesticides (those that are not persistent and do not bioaccumulate) (*e.g.*, species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska).
 - **CHARGE QUESTION 2b: Is there a way to identify species that may not always need to be fully re-assessed for each pesticide going through the consultation process (*i.e.*, by applying what we have learned from an analysis with another pesticides)?**
 - Once a species characteristics (*e.g.*, habitat) has been considered, what type of things regarding the fate properties of the pesticide would need to be considered (*e.g.*, aquatic half-life, mobility, bioaccumulation potential, *etc.*)?
 - Of these fate properties, how could they be considered (*e.g.*, a full assessment might not be needed for pesticides that have a $\log K_{ow} < 4$)?
 - What types of biological/ecological attributes of the species would need to be considered (*e.g.*, its habitat)?
 - Of these species characteristics, how can they be considered (this may be different for species and designated critical habitats) (*e.g.*, a full assessment might not be needed for species that live wholly or primarily in the open ocean, species only found on non-inhabited islands, and species found only in the arctic regions of Alaska, not present during windows of application; this may not apply to designated)?
- The pilot BE process relies on thresholds for mortality that are based on probabilistic effects endpoints (*e.g.*, 1-in-a-million chance of mortality based on the HC_{05} of a SSD or the lowest LC_{50}/LD_{50} values) compared to deterministic estimated environmental concentrations (EECs) (*e.g.*, 1-in-15 year peak EEC value). Additionally, sublethal thresholds are assessed using deterministic sublethal thresholds (*e.g.*, NOAECs or LOAECs) and deterministic estimated environmental concentrations (EECs) (*e.g.*, 1-in-15 year peak EEC value). The current approach in the BEs is comparing an exposure value to a threshold for possible exceedances [similar to a risk quotient approach (*i.e.*, exposure/effect)].
 - **CHARGE QUESTION 3b: Is there a way to utilize the thresholds that is more informative (for example, in the weight of evidence) and goes beyond a deterministic approach (moving towards a more probabilistic approach for assessing risks as recommended by NAS)?**
 - How could joint probability distributions of effects (the thresholds) and exposures (the EECs) be used to help inform the potential for risk?
 - Are there other probabilistic approaches that can help better inform risk at the individual and field levels?

- When making a “May Affect/No effect’ determination, what are some practicable methods to better determine where both direct and indirect effects are either ‘no effect’ or ‘discountable’ (extremely unlikely to occur)?
 - For example, could an action be “discountable” for certain species (*e.g.*, when there is no direct exposure or effects expected and no or insignificant/discountable effects to prey, pollinators, *etc.*).
- **CHARGE QUESTION 4b: Is there an efficient way to incorporate exposure durations into the analysis of potential effects?**
 - The pilot BEs currently compare all effects thresholds to peak EEC values. How can other durations of potential exposure be utilized and related to available toxicity studies (which are conducted under a range of exposure durations)?
 - Are there factors, other than duration, that should be considered when comparing the effects data to the EECs?

Estimating Exposure in Aquatic Habitats Represented by Flowing Bins 3 and 4

In the draft Biological Evaluations (BEs), effect determinations are made at the individual scale of biological organization. Consequently, the goal is to accurately predict maximum pesticide concentrations that may occur in different aquatic habitats utilized by listed species and are spatially and temporally relevant to the listed species. The modeling approach presented in the draft BEs leveraged EPA's current generic aquatic modeling approach by using the Pesticide in Water Calculator (PWC) shell, a combination of field-scale models (PRZM5/VVWM), to generate estimated exposure concentrations (EECs) for three generic flowing water bins of varying volumes and flow rates (Bins 2, 3, and 4). The Bin 2 estimates are intended to represent lower-flow habitats, such as first-order streams. When considered in relation to field-scale monitoring data, such as those obtained from edge-of-field (EOF) studies, model results should provide confidence in EECs for this bin. There is expected to be less confidence in applying this approach for deriving estimates for Bins 3 and 4, because processes that affect larger-scale concentration dynamics (*e.g.*, longitudinal dispersion) are not accounted for. The EECs derived for these higher-flow habitats in the draft BEs are extremely high and seem to defy both professional judgement and typical patterns seen in contaminant monitoring data.

In the context of watershed hydrodynamics, the three flowing bins represent aquatic habitats which would ideally be representative, for example, of streams that are sequentially connected within a watershed. While runoff and drift from a field adjacent to a Bin 3 and/or 4 waterbody can directly contribute loading, the EECs generated from these types of events are being characterized with Bin 2 EECs, as these EECs may be reflective of concentrations occurring before complete mixing within the Bin 3 and/or 4 waterbody had occurred. Initial modeling generated Bin 3 and 4 EECs that exceed those generated for Bin 2, which runs counter to expectations based on standard transport dynamics, *e.g.*, dispersive dampening of chemographic peak maxima as a pulse of contaminant moves downstream. Given the apparently unreasonably high EECs for Bins 3 and 4, a qualitative approach was considered in the draft BEs for use in assessing these bins. The approach relied on monitoring data to demonstrate a downward trend in the magnitude of peak exposures. Consistent with published studies showing a reduction in exposures as one moves down a watershed network, the approach showed a 5-fold reduction in exposure from Bin 3-like streams and a 10-fold reduction from Bin 3-like streams to Bin 4-like streams. The draft BE also applied a qualitative comparison of volumes and flowrates to suggest a reasonably conservative magnitude of exposure expected in Bins 3 and 4 as a separate line of evidence.

Charge Questions:

1. EPA explored several factors in using the PWC, including incorporation of a baseflow and use of the daily average instead of the instantaneous peak EEC. What are the strengths and weaknesses of these modifications? Are there other modifications that can be made and what are their strengths and weaknesses?
2. How appropriate are the methods used in the draft BEs to develop field/watershed sizes and waterbody lengths for these Bins? What reasonable alternatives could be used to model watershed processes that allow for accurate estimation of possible exposure concentrations (including the maximum) in these flowing bins based on product labeling?
3. For the bins (3 and 4) that represent larger flowing systems, what ways of incorporating the effects of dispersive mixing and/or peak desynchronization into concentration estimates are reasonable?

4. What are the strengths and weaknesses of alternative mechanistic or regression-based watershed models such as the Soil and Watershed Assessment Tool (SWAT), the Hydrological Simulation Program-Fortran (HSPF) and the Watershed Regressions for Pesticides (WARP) for simulating aquatic pesticide concentrations at the temporal resolution and national scales required for ESA assessment? Are there other watershed models that should be considered?
5. What is the desired and appropriate spatial scale for EECs for Bins 3 and 4? Specific PWC EECs were developed for HUC2 regions. Can or should the EECs for Bins 3 and 4 be at a finer spatial scale given a nationwide consultation?

Evaluation of Aquatic Exposure Modeling Estimates

In the Draft BEs, EPA employed an approach for flowing waters in an effort to approximate watershed processes. Regardless of the model employed, the EECs from any model need to be conservative (*i.e.*, protective of the species of concern) and scientifically defensible in order to be used for risk assessment purposes. Typically, for EPA's use of PRZM5/VVWM as a field-scale model for vulnerable waters (*e.g.*, headwater streams), this would be done by comparing model outputs to field monitoring data (*i.e.*, edge of field runoff studies), where pesticide monitoring data is associated with pesticide-applications under well-described conditions (*i.e.*, application rates, field characteristics, water characteristics, and meteorological conditions). However, for watershed modeling, which aggregates exposure across a larger area, field-scale monitoring data, and the associated well-described conditions for all locations in the watershed, can be extremely difficult to obtain and, as a watershed model aggregates exposure, it may not be necessary.

Available literature documents have evaluated watershed models, including the NAS-recommended model SWAT, using general and targeted watershed monitoring data that is focused on known high pesticide-use areas, provided the data are collected at a high enough frequency to adequately capture the peak exposure concentration along with variations in concentration in the receiving stream. Unlike field monitoring data, general monitoring data (*i.e.*, sometimes described as ambient monitoring data) often lacks background information on application rates and field conditions and can be problematic when used for comparisons to model-generated EECs. They may, however, provide a lower bound for model-generated EECs. Targeted watershed monitoring (*e.g.*, studies at a watershed scale that are targeted to areas of known high pesticide use, with a sampling frequency targeted to the timing of use and subsequent runoff events) has been proposed as a means to provide more than a lower bound, especially when such monitoring spans multiple years and can be tied to factors that drive pesticide transport from field to water bodies. Such data are used to complement the results from modeling, not as a substitute for modeling.

In the Exposure chapter of the 2013 NAS report¹, the NAS noted that "If pesticides are to be used without jeopardizing the survival of listed species and their habitats, the estimated environmental concentrations (EECs) to which the organisms and their habitats will be exposed need to be determined. Chemical fate and transport models are the chief tools used to accomplish that task." (p. 49) The NAS further went on to describe a stepwise approach to fate and transport modeling, commenting on the use of various models such as AgDRIFT, PRZM, and EXAMS (p. 52-54). The NAS then cautioned that "in evaluating models, general monitoring data and field studies need to be distinguished. General monitoring studies provide information on pesticide concentrations in surface water or ground water on the basis of monitoring of specific locations at specific times. The monitoring reports, however, are not associated with specific applications of pesticides under well-described conditions, such as application rate, field characteristics, water characteristics, and meteorological conditions. General monitoring data cannot be used to estimate pesticide concentrations after a pesticide application or to evaluate the performance of fate and transport models." (p. 54) Though not as abundant as general monitoring data, field-scale monitoring studies are available for many pesticides, including the three OPs. However, monitoring data with this type of supporting information are generally lacking at the watershed scale.

¹ National Academy of Sciences. 2013. Assessing Risks to Endangered and Threatened Species from Pesticides. The National Academies Press. Washington, DC.

Additionally, the general monitoring data, specifically at the watershed scale, sometimes include data sets which are spatially and temporally targeted to varying degrees with pesticide applications. Lastly, the NAS noted that “pesticide fate and transport models do not provide information on the watershed scale; they are intended only to predict pesticide concentrations in bodies of water at the edge of a field on which a pesticide was applied.” (p. 54) The NAS also noted that “different hydrodynamic models are required to predict how pesticide loadings immediately below a field are propagated through a watershed or how inputs from multiple fields (or multiple applications) aggregate throughout a watershed.” The NAS report did not provide additional discussion on the monitoring data requirements (*e.g.*, metadata such as use rates, location, and timing) needed to evaluate watershed models.

Given the distinctions above between field-scale and watershed-scale models, the question arises “how does one evaluate the results generated from a watershed model?” EPA is proposing to use of the following multiple lines of evidence to evaluate the range of scientifically-defensible EECs for each flowing bin: consideration of available edge-of-field monitoring data and edge-of-field modeled estimates from PRZM5; incorporation of results from multiple watershed models, as appropriate; and consideration of statistical approaches to estimate confidence bounds around general monitoring data that were collected at a greater than a daily time step (*i.e.*, SEAWAVE Q and bias factors).

Charge Questions:

1. In what ways are a “multiple lines of evidence” approach appropriate for evaluating the results from a watershed model? What would be the “lines of evidence” and sources of information?
2. How can different types of monitoring data be distinguished? What metadata requirements (*e.g.*, use info, sample frequency, etc.) can be used to distinguish types of monitoring data?
3. What roles can the various types of monitoring data play in the evaluation of results from a watershed model (*e.g.*, general monitoring doesn’t predict maximum but has other roles)?
4. What other approaches are available for evaluating results from watershed models?
5. To what extent can we rely on historical monitoring data when product labeling has changed and application-specific information is lacking?
6. Are there new or different types of monitoring that could be employed to further our understanding of aquatic modeling estimates?

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Subject: ESA check-in

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Code: 7033057092

- * Update on draft BEs
- * Actions from 2/19/16 meeting
- * Comments on CLA recommendations
- * Subgroups to work on options for Decision Framework, revisions to Step 1 and 2 thresholds
- * Next steps on pesticide consultation schedule planning
- * ESA stakeholder meeting
- * Status call with CBD and intervenors
- * Report to Congress
- *